

# H1N1 FLU—2009

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## HEARINGS

BEFORE THE

COMMITTEE ON  
HOMELAND SECURITY AND  
GOVERNMENTAL AFFAIRS  
UNITED STATES SENATE

OF THE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

APRIL 29, 2009

COORDINATING THE FEDERAL RESPONSE

SEPTEMBER 21, 2009

PROTECTING OUR COMMUNITY  
FIELD HEARING IN HARTFORD, CT

OCTOBER 21, 2009

MONITORING THE NATION'S RESPONSE

NOVEMBER 17, 2009

GETTING THE VACCINE TO WHERE IT IS MOST NEEDED

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Committee on Homeland Security and Governmental Affairs



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# CONTENTS

---

	Page
Opening statements:	
Senator Lieberman .....	1, 37, 79, 119
Senator Collins.....	3, 82, 122
Senator McCain.....	14, 99
Senator Tester.....	18, 107
Senator Voinovich .....	20
Senator Pryor .....	22
Senator Burris.....	24, 105
Senator Graham .....	25
Senator Kirk.....	102, 138
Senator McCaskill.....	110, 141
Senator Carper .....	113
Prepared statements:	
Senator Lieberman .....	153, 195, 248, 337
Senator Collins.....	155, 252, 341
Senator Burris .....	254
Senator Kirk with attachment .....	345

## WITNESSES

### Wednesday, April 29, 2009

Hon. Janet A. Napolitano, Secretary, U.S. Department of Homeland Security .	5
Anne Schuchat, M.D., Interim Deputy Director for Science and Public Health Program, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services .....	8

#### ALPHABETICAL LIST OF WITNESSES

Napolitano, Hon. Janet A.:	
Testimony .....	5
Prepared statement .....	157
Schuchat, Anne, M.D.:	
Testimony .....	8
Prepared statement .....	167

## APPENDIX

Responses to post-hearing questions for the Record from:	
Secretary Napolitano with attachments .....	174
Dr. Schuchat .....	186
Wayne Pacelle, President and CEO, Humane Society of the United States, statement for the Record .....	193

### Monday, September 21, 2009

Rear Admiral Michael R. Milner, U.S. Public Health Service, Regional Health Administrator, Region I, U.S. Department of Health and Human Services ...	40
Matthew L. Cartter, M.D., State Epidemiologist, Connecticut Department of Public Health .....	44
Hon. Peter J. Boynton, Commissioner, Connecticut Department of Emergency Management and Homeland Security .....	48
Stephen G. Jones, M.D., Director, Outpatient Medicine and Center for Healthy Aging, Chief Patient Safety Officer, Yale New Haven Health System .....	51
Julie A. Polansky, Parent, Vernon Public Schools .....	63

IV

	Page
Roseann Wright, Director, Waterbury Department of Public Health .....	66
Daniel Aloi, Manager, Business Continuity Services, Aetna, Inc. ....	69
Michael Kurland, Director, Student Health Services, University of Connecticut .....	72

ALPHABETICAL LIST OF WITNESSES

Aloi, Daniel:	
Testimony .....	69
Prepared statement .....	244
Boynton, Hon. Peter J.:	
Testimony .....	48
Prepared statement .....	228
Cartter, Matthew L., M.D.:	
Testimony .....	44
Prepared statement with attachment .....	204
Jones, Stephen G., M.D.:	
Testimony .....	51
Prepared statement .....	233
Kurland, Michael:	
Testimony .....	72
Prepared statement .....	246
Milner, Rear Admiral Michael R.:	
Testimony .....	40
Prepared statement .....	197
Polansky, Julie A.:	
Testimony .....	63
Prepared statement .....	236
Wright, Roseann:	
Testimony .....	66
Prepared statement .....	238

**Wednesday, October 21, 2009**

Hon. Janet A. Napolitano, Secretary, U.S. Department of Homeland Security .	84
Hon. Kathleen Sebelius, Secretary, U.S. Department of Health and Human Services .....	86
Hon. Arne Duncan, Secretary, U.S. Department of Education .....	90

ALPHABETICAL LIST OF WITNESSES

Duncan, Hon. Arne:	
Testimony .....	90
Prepared statement .....	279
Napolitano, Hon. Janet A.:	
Testimony .....	84
Prepared statement .....	255
Sebelius, Hon. Kathleen:	
Testimony .....	86
Prepared statement .....	266

APPENDIX

Chart submitted for the Record by Senator Lieberman .....	251
Responses to post-hearing questions for the Record from:	
Secretary Napolitano with attachments .....	284
Secretary Sebelius .....	309
Secretary Duncan .....	333

**Tuesday, November 17, 2009**

Anne Schuchat, M.D., Director, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services .....	124
Nicole Lurie, M.D., Assistant Secretary for Preparedness and Response, U.S. Department of Health and Human Services .....	127
Hon. Alexander G. Garza, Assistant Secretary for Health Affairs and Chief Medical Officer, U.S. Department of Homeland Security .....	130

V

ALPHABETICAL LIST OF WITNESSES

	Page
Garza, Alexander G., Hon.:	
Testimony .....	130
Prepared statement .....	387
Lurie, Nicole, M.D.:	
Testimony .....	127
Prepared statement with attachments .....	362
Schuchat, Anne, M.D.:	
Testimony .....	124
Prepared statement with attachment .....	348

APPENDIX

Chart submitted for the Record by Senator Lieberman .....	340
Combined responses to post-hearing questions for the Record from:	
Dr. Schuchat and Dr. Lurie .....	391
Jeffrey Levi, Ph.D., Executive Director, Trust for America's Health, statement for the Record .....	403
Letter to Hon. Kathleen Sebelius from Senator Collins, dated October 26, 2009 .....	409
Letter to Hon. Kathleen Sebelius from Senators Lieberman and Collins, dated October 27, 2009 .....	411
Letter to Senator Collins from Hon. Kathleen Sebelius, dated October 30, 2009 .....	414
Letter to Senator Lieberman from Hon. Kathleen Sebelius, dated November 10, 2009 .....	418



## **SWINE FLU: COORDINATING THE FEDERAL RESPONSE**

**WEDNESDAY, APRIL 29, 2009**

U.S. SENATE,  
COMMITTEE ON HOMELAND SECURITY  
AND GOVERNMENTAL AFFAIRS,  
*Washington, DC.*

The Committee met, pursuant to notice, at 10:05 a.m., in room SD-342, Dirksen Senate Office Building, Hon. Joseph I. Lieberman, Chairman of the Committee, presiding.

Present: Senators Lieberman, Pryor, Tester, Burris, Collins, McCain, Voinovich, and Graham.

### **OPENING STATEMENT OF CHAIRMAN LIEBERMAN**

Chairman LIEBERMAN. Good morning and thanks to all who are here. I particularly want to thank Secretary Janet Napolitano and Dr. Anne Schuchat for joining us today to discuss our government's response to the current outbreak of swine flu.

We are in the midst of a growing public health emergency whose ultimate course is not clear. But one thing is certain, and that is that swine flu is moving very quickly and harmfully from the first outbreak barely a month ago in a small village in Mexico to the first two cases in America confirmed in California barely a week ago, to the first American death, a 23-month-old child in Texas, announced and confirmed this morning. This flu has moved very quickly.

By yesterday afternoon in Mexico, more than 2,000 people have been hospitalized and 149 people have died from swine flu. This morning's numbers here in America are 66 confirmed cases in six States—New York, California, Texas, Kansas, Ohio, and Indiana. Globally, excluding Mexico and the United States, there are 39 confirmed cases in six other countries, including New Zealand, Spain, Great Britain, Germany, Canada, and Israel.

On Sunday, our government declared this to be a public health emergency. A day later, the World Health Organization (WHO) raised its pandemic alert to Phase 4. So this is no media-created or media-exaggerated story, as some have suggested. This is a genuine public health crisis.

The reassuring news, I believe, is that this is a case in which our government was prepared for the crisis, as best one can be prepared for a swine flu outbreak whose course is not clear, and our top government officials responsible for responding have done so, I think, with great strength and effect.

The fact is, as I said, that we do not know the course that this disease will follow. It is possible, as some have suggested, that the incidence of swine flu may diminish in the weeks ahead and then return with a vengeance in the flu season later this year.

So the American people are understandably anxious and want to know what they can do to protect themselves and what their government is doing and will do to protect them from swine flu.

This morning, we have two people with us who are really best prepared and most responsible for answering those questions. Secretary of Homeland Security Janet Napolitano is the person in our government given the authority and responsibility by statute and presidential directives to be the overall emergency manager of the Federal Government's response to this kind of threat. That reminds us that this newest of Federal departments created in the aftermath of the terrorist attacks of September 11, 2001, was from the start intended to be at the center of prevention and response not just to terrorist attacks but to natural disasters and to pandemic outbreaks, which in many ways mirror the effects of a potential attack by a weapon of mass destruction.

In the current attempt to limit the spread of swine flu, the presence within the Department of Homeland Security (DHS)—and not just the Federal Emergency Management Agency (FEMA), but also of agencies that concern and control immigration and access in and out and across our border, such as Immigration and Customs Enforcement (ICE), Customs and Border Protection (CBP), and the Transportation Security Administration (TSA) has been very important to consolidate the response, as has been the ongoing relations that the Secretary of Homeland Security has with State and local officials.

Dr. Schuchat is here this morning representing the Centers for Disease Control and Prevention (CDC), which works under the Department of Health and Human Services (HHS) in this case and its new Secretary, Kathleen Sebelius. That Department in turn leads the public health and medical response parts of the Federal Government plan now being coordinated by Secretary Napolitano.

I thank you both and all who have worked with you in the last several days for your rapid, strong, and reassuring response to this public health crisis. You have tracked the spread of the disease, identified and addressed new cases in this country, communicated your findings frequently to the American people, and implemented, or begun to implement, an array of preventive and response programs.

I think it is important to note for the record and hope that this gives some reassurance to the American people that, unlike other crises we have faced, pandemic flu is a threat that our Federal Government anticipated and planned. Nearly two decades ago, in 1992, the Institute of Medicine warned that emerging microbial diseases were a serious threat and that a number of modern demographic and environmental factors would facilitate rapid spread. We have seen since then global outbreaks of avian bird flu, West Nile virus, severe acute respiratory syndrome (SARS), and a host of other infectious diseases.

In response, in the early 1990s or mid-1990s, the CDC developed a National Emerging Infectious Diseases Strategy, and President

Clinton issued a presidential directive for Federal agencies to begin coordination for a national response to the growing threat of infectious diseases. But in 2003, we experienced a particularly bad seasonal flu outbreak and a particularly inadequate governmental response. After that, President Bush issued presidential directives, and in 2006, the Homeland Security Council agreed on and issued a National Strategy for a Pandemic Influenza Implementation Plan, which sets out a detailed road map for what to do in a crisis such as the swine flu outbreak we are in now.

States, supported by grants from the Department of Homeland Security and the Department of Health and Human Services, have pursuant to that plan developed their own plans for addressing pandemic flu. In fact, State and local governments have gone through demonstrations of preparedness exercises for exactly what we are going through now. But that does not mean that we do not have a lot of work yet to do and that we do not have to remain very prepared, ready, and agile, because we are facing a disease here whose course really is unpredictable.

This morning, we on this Committee are going to ask and hope that our witnesses will be able to answer some of the tough questions that remain on the minds of our constituents and on ours as well, and we look forward to your answers to those questions.

Again, I thank you for what thus far has been a very strong and a very reassuring response to a very real public health emergency. Senator Collins.

#### **OPENING STATEMENT OF SENATOR COLLINS**

Senator COLLINS. Thank you, Mr. Chairman. All of us are extremely concerned about the human swine flu outbreak that continues to grow in our country and around the world. While the disease has thus far been confined to six States, it is likely to spread further in the days to come.

As the Chairman mentioned, more than 150 people in Mexico are believed to have died from the virus, and just this morning the first death in our country was confirmed by the CDC.

There is also the dangerous potential that the flu strain will mutate into an even more deadly strain or one that is even more infectious. The American people have the right to expect that the Federal Government is doing everything possible to combat this potential pandemic, and to date, I would agree with the Chairman that it appears that our Federal officials have taken this threat very seriously and responded very effectively.

Today's hearing will give us the opportunity to learn more about what the Federal Government has done and what it plans to do to meet this growing public health threat.

As the Chairman mentioned, on Sunday the Department of Health and Human Services declared this incident a public health emergency. That alarmed many in the public. But as Secretary Napolitano has carefully explained, that was necessary to allow for the release of Federal resources to support our preparedness and response efforts. It also gives agencies greater flexibility to put rapid measures in place should the flu virus become an even more prevalent threat.

The declaration also places the Secretary of Homeland Security in charge of the overall Federal Government's response. Consequently, DHS must work closely with HHS and its component agency, the Centers for Disease Control and Prevention, in shaping our response, and I look forward to hearing the testimony of our witnesses today.

Congress has provided authorities and funding to strengthen our Nation's ability to respond to a pandemic incident, including the establishment of the Biomedical Advanced Research and Development Authority (BARDA), at HHS. I strongly supported the creation of BARDA and the increases to its funding.

To date, almost \$7 billion has been appropriated for Federal pandemic preparedness activities. This funding has been used for stockpiling antiviral drugs for the treatment of more than 50 million Americans. It has been used to license a pre-pandemic influenza vaccine, to develop rapid diagnostics, and to complete the sequencing of the entire genetic blueprints of more than 2,000 human and avian influenza viruses.

I mentioned that figure—it is actually 2,250—because it shows how many strains of flu we are already dealing with, and yesterday the President asked for an additional \$1.5 billion to combat this disease as part of the supplemental appropriations bill that Congress will soon be considering.

Despite these authorities and this funding, this Committee has uncovered weaknesses in pandemic flu planning and coordination in the past. Just last year, our Committee held a hearing on mass medical care that would be needed in the response to a pandemic flu or the detonation of a terrorist nuclear device. This hearing revealed some serious gaps in the Nation's capacity to provide mass care if thousands were to become ill.

The Committee has also held a hearing on HHS' development and procurement of the necessary vaccines, drugs, and countermeasures for public health emergencies just like this one. In addition, we previously looked at the poor communications and coordination between DHS and the CDC in an incident involving a Mexican citizen with a multiple-drug-resistant form of tuberculosis who was able to enter our country 21 times after being identified by the CDC.

These incidences lead us to several important questions that we will explore today. What has the Federal Government done thus far to protect the American people from this potential pandemic? Since the Department of Homeland Security has put relatively passive inspection techniques in place at the border, should more be done to protect against cross-border spread of the disease? How are the plans working? And have we encountered any unanticipated problems? What role should the State and local health departments play? What is the role for hospitals? I met with 21 hospital administrators from Maine yesterday who talked about the number of inquiries that they are fielding about this disease.

I particularly look forward to hearing about the status of the Federal Government's pandemic planning efforts. A critical part of this planning is the antivirals and other medical countermeasures from the Strategic National Stockpile that must be distributed rapidly to the public when needed. I would like to have more informa-

tion on how that distribution is working. Is it getting out to every State? How are the priorities set?

As the previous hearings in this Committee's investigation into the Mexican national with tuberculosis highlighted, coordination between DHS and HHS is essential, as is communication with Mexican officials. These are issues we will be exploring today as well.

Finally, let me indicate that I have been concerned about how the lack of appointees at top positions at HHS and DHS may be hindering the response. I am sure that HHS has been handicapped by the absence of a Secretary, and I am pleased that the Senate finally voted last night to confirm Governor Sebelius' nomination. But we still do not have a permanent head of the CDC, though we have many very capable individuals from the CDC, and DHS still lacks a Chief Medical Officer. I mention this because effective leadership is so important to the effectiveness of our response, and in this regard, I am very pleased with the leadership that has been shown so far.

Thank you, Mr. Chairman.

Chairman LIEBERMAN. Thank you very much, Senator Collins, and now we will go right to the witnesses, again with thanks for your accommodating and moving your schedule to be here with us today. Secretary Napolitano, thank you.

**TESTIMONY OF HON. JANET A. NAPOLITANO,<sup>1</sup> SECRETARY,  
U.S. DEPARTMENT OF HOMELAND SECURITY**

Secretary NAPOLITANO. Thank you, Mr. Chairman, Senator Collins, Members of the Committee. Thank you for the opportunity to testify on the national response to the H1N1 flu outbreak.

This is, as you have noted, a serious situation that we are treating aggressively. As President Obama said yesterday, it is a cause for concern but not for alarm. There is a lot we do not yet know about this outbreak, but we have been preparing as if we are facing a true pandemic, even though we do not know the ultimate scope of what will occur.

We also have been preparing with the understanding that this will be a marathon and not a sprint. We are going to be at this for a while.

Mr. Chairman, as you noted, the Secretary of Homeland Security is the principal Federal officer for domestic incident management, including outbreaks like this one. Under that role, we have been leading a true collaborative effort. HHS and the CDC also have lead roles on the health and science aspects of this outbreak. But every department of the Federal Government or virtually every one has a role to play.

For example, the Department of Education already has had a conference call with 1,400 participants on how to identify, and prevent H1N1 in school facilities.

The U.S. Department of Agriculture has been working to reassure people of the safety of our pork and pork products and to work with other countries with respect to the import of our pork prod-

<sup>1</sup>The prepared statement of Secretary Napolitano appears in the Appendix on page 157.

ucts. The U.S. Trade Representative I was with yesterday is doing the same.

As you noted, our State, local, and tribal partners are absolutely indispensable because on many questions they actually have the lead role. They are the first responders. We are now at the Department of Homeland Security conducting daily conference calls with these partners. Some days we have had as many as 48 States participating. We have 40-plus States participating on a regular basis.

Indeed, the public has a role to play here and a responsibility—a responsibility to cover our mouths when we cough, a responsibility to wash our hands regularly; if you are sick, not to go to work, not to get on a plane or a bus; and if your child is sick, not to send them to school to avoid infecting others.

I am pleased to be here with Dr. Anne Schuchat from the CDC. I want to commend the CDC for their work on this. They have been absolutely phenomenal to work with here and educating all of us about this particular strain and about flu outbreaks in general. The career public health officials there are doing a terrific job, as are the career officials at the Department of Homeland Security, and I want to praise them as well.

As you noted, part of the preparation is analyzing what we have with respect to antivirals. The National Stockpile has 50 million courses, and we are releasing 25 percent of the State portion already.

Senator Collins, you asked about who has been delivered already. Indiana, Nevada, Kansas, Kentucky, and Ohio have received antivirals from the stockpile. Today, antivirals are on their way to Arizona, California, Texas, and Utah. And I would be happy to supply the other schedule for the delivery. But that is the status as of this morning.

We have placed priority on States with confirmed cases of H1N1 and, of course, along the southwest border. But all States will ultimately get resources, and we intend to have complete delivery by May 3, 2009.

The State Department is also—

Chairman LIEBERMAN. Excuse me. That would be complete delivery of the 25 percent.

Secretary NAPOLITANO. Correct.

Chairman LIEBERMAN. Not of the full 50 million, right?

Secretary NAPOLITANO. Correct, Mr. Chairman.

Chairman LIEBERMAN. Thanks.

Secretary NAPOLITANO. The State Department also has been involved with the CDC. We have issued travel health alerts and travel warnings for non-essential travel to Mexico, and I anticipate those warnings and alerts will be up until the public health officials tell us they no longer need to be. Our actions are being guided by science and by what the public health community is telling us.

In addition, with respect to the Department of Homeland Security, we are moving forward in accord with planning and frameworks that have been worked on for several years. At the land ports and at the airports, Customs and Border Protection (CBP) is monitoring incoming travelers for possible H1N1 flu symptoms. Those who appear sick are put in separate rooms to be evaluated by health officials.

TSA also has protocols, similar protocols for air travelers who appear ill, and the Coast Guard is working with shipping companies with respect to possibly ill crew members.

The Travelers Health Advisory Notices made by the CDC tell travelers about the H1N1 flu, what to do if they have symptoms, and CBP is distributing tear sheets, cards, at the land ports and to those coming in on planes from Canada and Mexico. We are also distributing materials to passengers on cruises that stopped in Mexico, and, of course, TSA is posting all of this information at airport checkpoints.

The actions at the border are consistent with and match the recommendations of the CDC and the World Health Organization, and here I want to pause a moment. There has been some question raised about closing the borders. First, the actual statutory authority is not with respect to closing an entire border. It is with respect to closing a particular port or series of ports. But I think as Dr. Schuchat will explain in greater detail, making such a closure right now has not been merited by the facts. It would have very little marginal benefit in terms of containing the actual outbreak of virus within our own country.

As I mentioned, our coordination with State and local partners is very robust. We are also coordinating with our international partners and with the private sector. I have been in phone contact with the governors of many of the States, and I will be making another series of calls this afternoon. I have spoken with my direct counterparts in Mexico and Canada. We have adopted in many respects a tri-national approach to this because the virus itself does not know when to stop at a border or not. And the Private Sector Office and the Infrastructure Protection Office of the Department are working with the private sector informing them that it is time to dust off their pandemic flu plans, if they have not exercised them, to get them ready and to focus on business continuity planning as we move forward.

Within the Department, we are working to prepare the health of our own employees. We are pre-positioning antivirals as well as personal protective equipment in case those are needed. And we continue our operations in full force.

Let me conclude with this: Every American has a responsibility here with this outbreak. Every community has a responsibility to work on and get the word out about preparedness. Obviously, our thoughts, prayers, and sympathies go out to the families already affected by this H1N1 virus, but our goal is to make sure that the country is prepared, that we respond with alacrity and with efficiency to the current outbreak.

Thank you, Mr. Chairman.

Chairman LIEBERMAN. Thanks, Madam Secretary, for an excellent opening statement.

Dr. Schuchat, thanks to you and your colleagues at CDC for your service all the time, but really for your very impressive ability to communicate facts to the American public at this time, which is most important. Please proceed.

**TESTIMONY OF ANNE SCHUCHAT, M.D.,<sup>1</sup> INTERIM DEPUTY DIRECTOR FOR SCIENCE AND PUBLIC HEALTH PROGRAM, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Dr. SCHUCHAT. Thank you. Good morning, Chairman Lieberman, Ranking Member Collins, and other distinguished Members of the Committee. I am Dr. Anne Schuchat, the Acting Deputy Director for CDC's Science and Public Health Program. I appreciate the opportunity to join the Secretary and to tell you about the current steps of what is going on and what we are doing about it. Our hearts go out to the people of the communities in the United States, in Mexico, and around the world who are coping with this challenge, and I think all of us this morning are thinking of the family in Texas who did lose a loved one.

People are concerned, and we are concerned as well. We are responding aggressively at the Federal, State, and local levels to understand the complexities of this outbreak and to implement control measures. Our aggressive actions are possible in many respects because of the investments and the support of the Congress and the hard work of State and local health officials at the front line across the country.

Flu viruses are extremely unpredictable, making it hard to anticipate the course that this outbreak will have with any certainty. We do expect increases in the number of cases, the number of States that are affected, and the severity of illness. And during this uncertainty we hope that we can remain clear in communicating what we do know, what we are doing to protect the health of Americans, and help Americans understand the steps that each one of us can take to protect ourselves, our families, and our communities.

Influenza arises from a variety of sources, and in this case, we have determined that there is a novel 2009 H1N1 virus that is circulating both in the United States and Mexico that contains genetic pieces from four different virus sources. Additional testing is underway on this virus, including the complete genetic sequencing. CDC has determined that this virus is contagious. It is spreading from human to human, similar to seasonal influenza, likely through coughing and sneezing. Sometimes people may become infected by touching something with the flu virus on it and then touching their mouth or nose. But there is no evidence to suggest that this virus has been found in swine in the United States, and there have been no illnesses attributed to handling or consuming pork. There is no evidence that you can get this new influenza from eating pork or pork products.

I want to reiterate that as we look more intensively for cases, we are finding more cases. We fully expect to see not only more cases, but also potentially greater severity of illness. The specific numbers are really less important in understanding the outbreak than the more general patterns that we use to help guide our interventions.

Aggressive actions are being taken. They are being taken here and around the world. We are working very closely with State and local public health officials in the United States on the investigation to implement control measures. We are providing both tech-

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<sup>1</sup>The prepared statement of Dr. Schuchat appears in the Appendix on page 167.

nical support on the epidemiology as well as the laboratory support for confirming cases. We are also working with the World Health Organization, the Pan American Health Organization, and the governments of Mexico and Canada on really understanding and responding to this outbreak.

There is a tri-national team that is working in Mexico, including members from CDC, to better understand the outbreak and enhance survival and lab capacity so that we can answer critical questions, such as why the cases in Mexico appear to be more severe than the initial ones that were seen in the United States. We are working closely with Secretary Napolitano and other Federal partners to ensure that our efforts are coordinated and effective.

CDC has issued numerous health advisories for individuals, health care practitioners, schools, and communities, and these continue to evolve as our understanding of the situation changes. On Monday, CDC issued a travel health warning for Mexico, recommending that travelers defer non-essential travel to Mexico. We are also evaluating information from other countries and will update travel notices as necessary.

But, as always, people with flu or flu-like symptoms should stay home and not attempt to travel. In fact, a key message from us is that there is a role for everyone to play in this outbreak. At the individual level, it is important to understand how each one of us can help prevent respiratory infections. Frequent hand washing is effective to reduce transmission of disease. If you are sick, stay home. If your kids are sick, have a fever and flu-like illness, they should not go to school. And if you are ill, you should not get on an airplane or public transport to travel. So taking personal responsibility for these things will help reduce the spread of this new virus, just as it helps reduce the spread of other respiratory illnesses.

It is important for people to think ahead about what each one of us would do if this outbreak deepens in our own communities. Communities, businesses, schools, and local governments should plan now for what to do if cases appear where you live or work. For example, parents should prepare for what they would do if faced with a temporary school closure. Do you have all your plans in place?

We also have issued additional community guidance to clinicians, laboratory workers, and other public health officials so that they know what they should do if they see cases in their community. All of these specific recommendations, as well as other regular updates, are on our website—[www.cdc.gov](http://www.cdc.gov).

CDC maintains the Nation's Strategic National Stockpile of medications for the eventuality that they may be needed in a situation such as we face. As part of the pandemic preparedness efforts that the Senator was speaking about, the U.S. Government purchased extensive supplies of antiviral drugs, and our preliminary testing is reassuring that the virus that is circulating can be treated with the drugs in our stockpile. That is a really good thing.

We have released one quarter of the States' share of the antiviral drugs and personal protective equipment to help States prepare to respond to the outbreak. We also, working with the Food and Drug Administration (FDA), have achieved an emergency use authority

to facilitate the effective use of some of these materials. Distribution has begun, starting with the States where we already have confirmed cases, and the Department of Defense and individual States have also stockpiled these antiviral drugs.

Whenever we see a novel strain of influenza, CDC begins work toward the development of a vaccine in case one needs to be produced. CDC worked to develop what we call a "vaccine seed strain" that is specific to this novel virus, which is the first step in vaccine manufacturing. We have initiated steps so that, should we need to make a vaccine as a government, we can work towards that goal very quickly. Rapid progress will be possible through the combined efforts of CDC, the National Institutes of Health (NIH), FDA, BARDA, and, of course, the manufacturing community.

Finally, it is important to recognize and acknowledge that with the strong support of the Congress, there have been enormous efforts in the United States to prepare for this kind of outbreak and to prepare really for pandemics in general. Our detection of this strain in the United States came as a result of that investment. Our enhanced surveillance and laboratory capacity are critical now in understanding and mitigating this threat. While we must remain vigilant throughout this and subsequent outbreaks, it is important to note that at no time in our Nation's history have we been as well prepared as we are today.

As we face the challenges in the weeks ahead, we look forward to working closely with Congress to best address the evolving situation, and I look forward to answering your questions.

Chairman LIEBERMAN. Thanks very much, Dr. Schuchat. That was very helpful. I appreciate what you have said and I agree with you, though, that we are fighting a serious public health challenge, and we do not know now exactly what path it will follow. I want to paraphrase what you said. At no time in our Nation's history have we been better prepared to deal with exactly this kind of crisis, and I appreciate what all of you at CDC do to put us in that position.

We are going to have 7-minute rounds of questions for each Senator, and I will begin now.

Let me ask you a few of the medical questions. You are right, we are fortunate to have 50 million—"doses," is that the right term?

Dr. SCHUCHAT. It is actually "courses."

Chairman LIEBERMAN. "Courses," right, of treatment.

Dr. SCHUCHAT. Yes.

Chairman LIEBERMAN. Of two drugs, I gather: Tamiflu® and Relenza®, both of which have been found to be effective, and this is treating swine flu if it occurs.

Do you think now that the 50 million courses are adequate to the need? And if not, what should we be doing, both on your end and on ours, to finance an increase of that inventory?

Dr. SCHUCHAT. The estimates of how much was needed for the Strategic National Stockpile involved a mixture of Federal and State responsibilities, and our planning assumptions were to make sure that we had enough antiviral medications to treat 25 percent of the population. Among our 50 million courses, there are 6 million that are designated for strategic priorities, things like containment, should that have been possible. And I think we are re-evalu-

ating the issue of whether additional antivirals may be needed in the future. We are so fortunate that we made those investments and that, with the coordination and planning, we have been able to deploy the 25-percent portion of the assets. We do not really know if we are going to need to use large numbers of them, but I think we are ready if we do.

Chairman LIEBERMAN. There is a feeling, in response to some of the things that experts like yourself have said, that it is possible that the current outbreak will diminish as what we have come to call "flu season" ends, but then may pick up again in a much greater way next flu season later this year. Is that accurate? Do we know that with a reasonable certainty? Or is it possible that the swine flu will just keep on expanding and going further?

Dr. SCHUCHAT. Unfortunately it is very unpredictable. Seasonal flu has a fairly clear season and really goes away in our summer months. And in pandemics that have been studied in the past, sometimes there have been second waves—one spring, and then a second wave the next fall or winter. So we do not know what pattern we will see, whether cases will continue to increase or whether there will be a decline.

What we would like to communicate is that if we do see a decline, that does not necessarily mean we are out of the woods. We need to be planning and preparing for an eventual recurrence, and that is part of the thinking involved with the vaccine discussions that we are having right now.

Chairman LIEBERMAN. Right. And, again, I am sure the public understands this. We are talking about two things: We are talking about the antivirals, which are a treatment for people who come down with swine flu; and then we are talking about trying in a really aggressive schedule to develop a vaccine which hopefully would prevent the flu from spreading.

Dr. SCHUCHAT. Yes, that is right, Senator. The antiviral drugs or medicines, like Tamiflu<sup>®</sup> and Relenza<sup>®</sup>, can treat an influenza illness. We have influenza vaccines that we use every year to treat the seasonal flu, and we are discussing, across government and the scientific community, the issue of developing a vaccine specific to this new influenza virus that has been detected.

Chairman LIEBERMAN. I know that President Obama has requested an additional \$1.5 billion to be prepared to deal with this. I presume that a good amount of that money is meant to be available for either acquiring more antiviral courses and investing in the development of the vaccine for the next flu season. Is that right, Secretary?

Secretary NAPOLITANO. Yes, Mr. Chairman. And I think it is a rough estimate, and we just wanted to have a pool of money, as it were, that could be drawn down quickly.

Chairman LIEBERMAN. Let me ask you now one of the questions that my constituents at least asked me, which you touched on in your opening statement, which is this: Since this swine flu outbreak began in Mexico, and a lot of the stories we are hearing in the media about people who seem to have it, including now some suspected cases in Connecticut, more often than not—certainly in a disproportionate number of cases—involve people who visited Mexico or had some contact with somebody who did. Why not,

within the terms that you described statutorily, close the border, and both ways, both people coming from Mexico to here or Americans—in other words, why not just say no, you cannot go to Mexico from the United States for some period of time, not just have a travel advisory?

Secretary NAPOLITANO. Well, I am going to ask Dr. Schuchat to respond because we have been taking our guidance there from the public health community as to when the facts merit actually closing a port. What is the best thing to do for the safety of the American populace?

Chairman LIEBERMAN. Dr. Schuchat, go ahead.

Dr. SCHUCHAT. Thank you. This is a reasonable question that people are asking, and we want to make sure we get clear information out.

There has been a formal policy analysis of this issue, including analysis with infectious disease modeling, and the estimates are that in 2007 this effort was carried out.

Chairman LIEBERMAN. OK. Was this done now or previously?

Dr. SCHUCHAT. And there have, of course, been updates as new information comes along, with just that idea of whether it would be effective to try to close or partially close the border. And the estimates were that if there were cases in Canada or Mexico, within days the ability to stop that introduction into the United States would be gone.

So what we have been doing is really looking at the epidemiologic patterns, the spread of disease, where it is occurring, and the scientific assessment is the most effective strategy right now to focus on where we have illness, those families and the communities around them, and that it is really not an effective approach to try to block things at the border.

Of course, we have our efforts to suggest to the travelers from the United States to defer non-essential trips to Mexico, and we have a strong partnership with the Customs and Border Protection staff to recognize ill passengers or travelers and deal with them.

There is a personal responsibility element in all of this in terms of when each of us is ill not getting on an airplane or crossing a border. In fact, the Director General of the World Health Organization has said, at this point the most effective assets really need to be focused elsewhere, and the border is a real diversion.

Chairman LIEBERMAN. Let me just follow up, because the response from my constituents to the answer that I think I heard you give, which is the swine flu is already here so we have to contain it here, and closing the border or stopping people from going to Mexico or coming from Mexico to here does not help at all.

Their response to that is, well, the more people who go back and forth between Mexico and here, isn't it more likely that there will be more contagion occurring? What do you say to that from a medical point of view?

Dr. SCHUCHAT. From a medical point of view, I think that is not the case. I think it is reasonable for people to be asking that question, but that is where that infectious disease modeling goes on. We have infectious cases or confirmed cases in many communities in the United States, so the probability of exposure from someone who has no contact with Mexico is also an important issue right now.

So I think it is reasonable that they are asking, but we do not think that is a good strategy.

Chairman LIEBERMAN. OK. I am sure that others on the Committee will want to continue this discussion. Thank you.

Senator COLLINS. I will continue it.

Chairman LIEBERMAN. Senator Collins, it is all yours.

Senator COLLINS. Madam Secretary, you have explained, as has the doctor, why you do not think the border with Mexico should be closed, but there are other steps that could be taken to enhance the screening at the border.

Now, last year, Customs and Border Protection inspected almost 400 million travelers coming across our borders, so we are talking about a very high volume. And as I understand it, DHS has instructed the border officials to use passive surveillance at our ports of entry to try to identify individuals who could have symptoms of the flu. But other countries are being far more aggressive in their screening. Singapore, Thailand, Japan, Indonesia, South Korea, and the Philippines are all using thermal scanners. Those were also used during the SARS crisis in 2003 at airports, and as I understand it, these scanners are able to detect if a passenger has a fever, and the person can be set aside.

Now, I heard you on television say that you did not think the technology was good enough, but, in fact, we have half a dozen countries who are employing that. It seems to me that there are steps that could be taken to strengthen the screening at the border if closing the border is neither practical nor called for, according to the public health assessment. Why aren't we doing more to try to screen?

Secretary NAPOLITANO. Senator, thank you. Actually, the term "passive surveillance" is really not an accurate depiction of what is going on. What our CBP officers are doing is actively monitoring travelers that are attempting to cross the border, asking for those who appear ill, asking questions about whether they are ill, their travel history and the like. And there is a protocol that is in place for how that is done. We take our guidance, as I said before, from the public health officials as to what steps really would work and would be effective.

With respect to the thermal scanners, they are not always accurate. They are not always as precise as one would wish. But, in addition, you have travelers who actually have the flu who do not have a temperature. So they do not really help you sift out travelers who are ill from those who are not. And so the recommendation to us has been that would not be a particularly useful technology. I do not know if Dr. Schuchat has anything to add there.

Dr. SCHUCHAT. Yes, that is exactly right. Some countries are doing this now, and, of course, during the SARS experience, this was done quite a bit. The science right now really does not hold that up. I was personally scanned many times during the SARS issue when I was in China, but I think that we are really trying to follow the science here.

Senator COLLINS. I guess my concern is that even if that technology is not perfect, even if individuals who have the flu do not necessarily have a fever at the early stages, it seems to me using technology to try to identify some of the individuals would make

sense. And if you have six other countries doing it, then clearly there must be some value in identifying individuals who have fevers, since that is a common symptom, who could be set aside for additional screening. It just strikes me that—and maybe “passive” is the wrong term, as the Secretary suggests, but, in fact, the reports that we are getting is that the volume is such that it is very difficult for officials at the border who are not medically trained, after all, to do this kind of selection process or surveillance.

Dr. SCHUCHAT. I just want to make sure that I am clear. We are looking at the pattern of illness that we have here in the United States and the many places within our own borders where there are now laboratory-confirmed cases and what that tells us about our risk within the United States. And I think much of our attention comes from previous outbreaks and modeling and suggests that the focus is really in looking aggressively for cases here in the United States, responding in our own communities.

And so I think it is understandable for there to be questions about this, and the issues in countries that have not yet seen cases may be quite different. But here in the United States we are really focusing on what we can do within our own communities where we have several States with active cases.

Senator COLLINS. Doctor, let me ask you a more fundamental question. I believe that most Americans would be surprised to learn that 36,000 people every year die from the regular seasonal flu and that regular seasonal flu produces some 200,000 hospitalizations. Those statistics were surprising to me, and I suspect that they would be to most Americans.

What makes this particular strain of flu particularly dangerous and alarming?

Dr. SCHUCHAT. This situation that we are experiencing now reminds us that seasonal flu is a bad thing also—as you say, the 36,000 estimated deaths—and we make intense efforts to try to protect people from seasonal flu. The difference right now is that we are dealing with a novel virus. We do not know yet all of the characteristics of how it will behave in human populations, but we know that it is a virus that has not been around before, that we have not seen immunologically. So what we think is that the general population does not have immunity to this virus.

With seasonal flu, a good proportion of the population has some immunity because of the viruses that circulate every year, and one of the risks for future pandemic potential is a new virus that there really is not widespread population immunity to.

We are trying to understand now whether some people who are older seniors might actually have some protection, some natural immunity against this particular virus because perhaps it is close enough to things that were circulating a long time ago. But we really worry about that novel strain that is not like the circulating seasonal flu strains.

Senator COLLINS. Thank you. Thank you, Mr. Chairman.

Chairman LIEBERMAN. Thanks very much. Senator McCain.

#### **OPENING STATEMENT OF SENATOR MCCAIN**

Senator MCCAIN. Thank you, Mr. Chairman, and again, I want to thank Secretary Napolitano and Dr. Schuchat also for doing a

fine job in keeping the American people informed, coming here and testifying, appearing on national television. This is something that really has Americans deeply concerned, and understandably so. Thank you for your continued communication with the American people.

Madam Secretary, if we close the border with Mexico—obviously you have the responsibility to make that recommendation. I would imagine it would be a presidential decision. And you said that conditions right now do not warrant the closure of the border. What conditions would warrant that you recommend that the border between the U.S. and Mexico be closed?

Secretary NAPOLITANO. Well, if the CDC told us that closing the border would have a significant impact on the prevention of disease within our country, I think that would be a highly relevant factor. But the analysis has been that closing ports, closing the border, would not have that kind of preventive impact at this stage.

Dr. SCHUCHAT. And I would actually like to add to that. Some of the planning that we have been doing over the years past had the primary assumption that a new strain of influenza was going to come from very far away. We were worried about the H5N1 bird flu strain of influenza, and we wondered, if we see illness in a very distant place, what should be our posture.

Senator MCCAIN. But I say with some respect, Dr. Schuchat—and I do not have much time—if we are not going to close the border because the conditions do not warrant it, what conditions do warrant the closure of the border?

Dr. SCHUCHAT. What I am trying—

Senator MCCAIN. Are there any conditions that would exist that would? For example, the European Union is just recommending that there be no flights from Europe to Mexico. And I would imagine that there will be reciprocal action.

I think the American people need to know, if we do not have to close the border now—and with all due respect, we all know, Madam Secretary, that millions of people move back and forth across the border on a daily basis. And just observing them, I think, is certainly not totally effective, to say the least. What conditions would prevail that would say we need to close the border between the U.S. and Mexico, if any?

Dr. SCHUCHAT. I do not think there are any.

Senator MCCAIN. You do not think there are any. I thank you. And, by the way, I think it is appropriate, again—as Senator Collins pointed out—36,000 people do tragically die every year from the flu that we experience in this country. What do you think the percentages are, Dr. Schuchat, the likelihood that it tails off, as you said in your prepared statement, during the summer but then we find a reoccurrence takes place when flu season begins again?

Dr. SCHUCHAT. Unfortunately, we really cannot predict exactly what is going to happen. There are many things that we will be doing to try to understand the probability that there will be another wave. There are issues like looking in the Southern Hemisphere at the pattern of disease that they have. We can also do some things to try to understand our population's immunity. Did we already see this new strain go through a lot of the population and develop some protection?

So there has been planning in terms of the research and the epidemiologic studies that could help us better predict. But even with all of those, we will not be able to perfectly predict. So our posture is to prepare and to be ready if things do get worse.

Senator MCCAIN. Is it possible, given your experience, to tell me your personal prediction?

Dr. SCHUCHAT. My personal prediction is that I will get in trouble if I make a guess. [Laughter.]

Senator MCCAIN. Well, that is a good point.

Madam Secretary, Dr. Schuchat's point about no conditions warranting closing the border is a very important one. Then if that is the case, I really hope that we would pursue vigorously better technological and scientific and, frankly, closer observation of people going across the border than is presently the case. And I know that we have a huge border with Mexico, and it would be hard to implement immediately. But if the possibility is that we may be in for the long term here, as Dr. Schuchat, I think very appropriately, refuses to predict but is a possibility, then we ought to look at ways of checking people more carefully as they go across the border between the U.S. and Mexico.

I know you know that the report of the first death from swine flu in the United States just took place in the State of Texas, so I think we need to—and I believe you are—maintain a careful balance between not causing panic out there amongst the American people, but at the same time making them aware of the implications of this threat, much of which is really not totally known to us. But we have experienced SARS and other viruses in the past and have been able to gain some control.

Does the present vaccine, Dr. Schuchat, that a lot of Americans routinely get have any beneficial effect on H1N1?

Dr. SCHUCHAT. Based on the studies that have been done so far of this new virus, we do not expect there to be protection. There are some additional things that we are looking at to understand whether our pessimistic prediction might be wrong and, in particular, looking at serum from certain populations to understand whether there might be any cross-protection. But based on the laboratory testing that has been done so far, we do not expect there to be any cross-protection.

Senator MCCAIN. In a best-case scenario, how long would it take us to discover and develop a vaccine that would combat H1N1?

Dr. SCHUCHAT. There are active efforts right now. At CDC our role is to develop the vaccine strain that is handed off to industry. The steps after that would be pilot lot developments by manufacturing and studies really undertaken by NIH and FDA to make sure that we know how to administer the vaccine, the dosing, and whether or not you need what is called an adjuvant to increase the immune response.

If everything goes well, production could lead to availability as early as September, but, of course, with influenza vaccine production, or even seasonal flu, everything does not always go great smoothly.

So there are lots of entities meeting and taking steps to aggressively move forward and being ready to produce a vaccine should

we need to. But even with the best case and decisions made quite promptly, we would not have product until the fall.

Senator MCCAIN. Madam Secretary, I hope you will keep revisiting this issue of whether we need to close the border or not.

I thank you, Mr. Chairman. I thank you all for your fine work.

Chairman LIEBERMAN. Thanks, Senator McCain. I must say I did not come here this morning feeling—and I still do not—that we have to close the border with Mexico. But I am surprised at your answer, Dr. Schuchat. In the second round, I will ask you more questions about it, that you cannot foresee a circumstance in which we would possibly want to do that. My own feeling—I am not a doctor, to say the obvious—is if we can contain the spread of the flu here, one thing we might want to do, just as the Mexican Government is thinking about, is stopping public gatherings, even in the worst case, closing down parts of the business sector in Mexico City because they do not want it to be communicated. There is a kind of common sense that says, well, if it reaches that point, don't we want to avoid increasing the probability of contagion, even for a temporary period of time? I understand there would be horrendous economic and personal effects of this on both sides of the U.S.-Mexican border. And, of course, this death that occurred today in Texas, this child apparently went from Mexico to Texas. So presumably there was some connection there.

Secretary NAPOLITANO. Mr. Chairman, first of all, you are right, and this situation keeps changing. For example, the CDC is going to announce that four other States now have confirmed contagion: Arizona, Nevada, Massachusetts, and Michigan. They are going to announce now 91 confirmed cases. We cannot anticipate that those sorts of reports now are going to continue. But the decisions about closure of events, closing a school, not having a meeting, that sort of thing, those primarily are generated at the local level based on the circumstance and environment at the local level.

That is why it is so important that we work with cities and States in terms of their own implementation of their criteria for when they would close or not close. And, again, it needs to be informed by the size, the extent of contagion, and what you can prevent by making a closure.

Returning to Senator McCain's question, obviously we will watch those ports of entry very closely, and I will be happy to share with you the protocols that have been given to our CBP officers of what exactly they are supposed to be doing at the ports.

Chairman LIEBERMAN. Thanks, Secretary. I just hope that—and I understand, Dr. Schuchat, you are not a political person. You are giving your best medical advice, and we ought to give it respect. But I hope we will keep open, as we watch the course of this disease, the possibility that we might want for some period of time to close some of the ports of entry between Mexico and the United States, and if not that, then to greatly ramp up the kind of review of people going back and forth that we are doing at this point. But I am delaying my colleagues, and I thank you for the responses.

Senator Tester, you are next.

**OPENING STATEMENT OF SENATOR TESTER**

Senator TESTER. Thank you, Mr. Chairman, and I want to thank both participants here today for their information. It is good stuff. And I think that we do have a serious problem that we face, and I think it is partially because of your good work and your leadership that this will be minimized as much as possible. I think so far the response in the country has been good from your end and from the local level and everywhere in between, and I think it is good news when all parts of government step up to the plate and really do their job, potentially to rethink their flu response plans and things like that. That is good news.

I think that the best news is, as I think we all recognize, that there are still some gaps. There are still some things we need to iron out. I come from a frontier community in a very rural State with a border of 545 miles with Canada in this particular case, with many ports of entry between Canada and Montana, and I think we all realize how important those ports are. We all understand how important trade is. And we also understand how serious this potentially could be as it starts to unfold. But we need to make sure we take the right precautionary trail as we go forth here.

Some have said we need to close the border. We have heard today that potentially is an option until this blows over. I tend to agree with the good doctor. I think that we need to let science lead the way here and make reasonable decisions, rational decisions based on sound science, mainly because we already have some confirmed cases here in the United States and we see how it is starting to expand throughout the United States, with four more today.

Secretary NAPOLITANO, you talked in your opening remarks about what is going on on the border right now from a perspective of the cars and trucks coming across the line, that you—let me see. How did you put it? You were monitoring, and the folks who look sick, you are pulling them in. What exactly do you do after that? Are they looked at by a medical doctor? What transpires then?

Secretary NAPOLITANO. Yes, Senator, they are put in an isolation room, basically, and some of our ports have a public health official right there. Other times, they have to call and have one brought over to examine the individual.

Senator TESTER. So how quickly could they know if these folks have some other kind of flu or this kind of flu?

Secretary NAPOLITANO. Well, fairly quickly. I mean, I think the longest wait we have had to date has been 2 hours.

Senator TESTER. What is the incubation period for this, do you know? That is maybe directed at the doctor.

Dr. SCHUCHAT. This is a novel virus, so we are beginning to characterize the incubation period. And from the information we have so far, it looks to be between 2 and 5 days.

Senator TESTER. OK.

Dr. SCHUCHAT. But that is changing as we get more information.

Senator TESTER. In many of the rural States around this country, we have critical access hospitals that have fewer than 25 beds. Oftentimes, there is a nursing home attached to them. Although I have heard that this attacks healthy adults, we see the first confirmed death is an infant, a 2-year-old. What are you recommending critical access hospitals that have nursing homes attached

to them do to help stop the spread of a potential contaminant coming in, a person, to the elderly population that might be living in those nursing homes?

Dr. SCHUCHAT. CDC has been issuing many new guidance documents and pushing them out to the clinical community—the doctors and nurses, the laboratories, and hospital workers—so that they know about infection control practices—the kinds of “droplet precautions” is sort of one of the terms we use; the things about how to diagnose cases, making sure that patients are isolated, that they will not be in a room with someone else and able to spread.

But what we are also doing is making sure that we do not get dogmatic, that we learn from what we are seeing, and that we update recommendations when guidance needs to be changed because of the events that we observe.

Senator TESTER. Can you tell me, how many confirmed cases are there in Canada? I do not know that I have read that.

Dr. SCHUCHAT. Unfortunately, I do not have Canada’s counts myself today.

Secretary NAPOLITANO. The last I heard was several, some were in Nova Scotia and some were in British Columbia. So they were spread out.

Senator TESTER. All around the country. Do you have the ability to—CDC or do others have the ability to—my guess is if you get a group of folks that get sick, it could become bigger pretty quick. So it could affect communities, a certain community much greater than 150 or 200 miles away in a State. Are there agreements to be able to transfer medical personnel between hospitals or States to make sure we have the medical personnel that can meet the need?

Dr. SCHUCHAT. There are some of those agreements. In fact, during the SARS epidemic in Canada, there were American doctors that went and helped them. State to State, we also have those kinds of approaches.

Senator TESTER. Who is “we”? Is that done at the local level, or is that done at your level?

Dr. SCHUCHAT. Well, no, I think it is more at the State level. But the issue that is important to realize, though, in our pandemic planning we really had to recognize that the way pandemics of influenza unfold, many communities may be affected, and so few places are likely to want to spare their professional staff because they may be just around the corner. So this is where our guidance helps clinicians know what to do, even with a reduced workforce.

In particular, we may see a point in the future where we have to have simpler ways to care for people—only the most sick coming to the hospital and such.

Senator TESTER. Do you see any challenges dealing with critical access hospitals that are going to over and above what you would see in urban areas? And what are they? And how will you deal with them?

Dr. SCHUCHAT. What I would like to say is that we do not know whether things will be better or worse in those kinds of communities. It may be that the more remote communities will not have the kind of problems that we are seeing in New York City, for instance. But another part—well, there is planning on trying to sort

out how the Federal Government can enhance what is available at the State or local level in terms of the medical surge issues.

Senator TESTER. Thank you, Mr. Chairman. Thank you both.

Chairman LIEBERMAN. Thank you, Senator Tester. Good questions. Senator Voinovich.

#### OPENING STATEMENT OF SENATOR VOINOVICH

Senator VOINOVICH. First of all, I would like to thank both of you for the quick action that you have taken and trying to walk that fine line in terms of making sure people have good information and at the same time not be panicked by this. I think that is very important.

But, also, I think that we should be comforted, because Congress and the former Administration understood how important this issue of pandemic was, that we do have antiviral drugs available to us to respond to the folks that are getting sick.

Some simple questions that people are asking—this is not swine flu. It is H1N1. Is that what we say? And we have a lot of pork producers in Ohio that have called me and have said, please clarify for the public that they should not stop buying pork, or that countries that are having our pork exported to them should not stop having it being exported. They said, “We are hurting now, so please clarify that.” So it is H1N1 that we are talking about.

The other thing is thank you very much for your quick response to the situation that we had in Ohio. Because you need the help of the local officials so much, are you confident that they have the proper protocol in terms of how to identify this and deal with it, and then getting into the question of when or not you would, for example, close a school? When I was president of the student body at Ohio University many years ago, I had to cancel Homecoming and Mother’s Weekend, and it was not a lot of fun for me. But we decided that we wanted to keep folks from coming into the campus. And you are going to have instances, throughout the United States, where people are going to take local action, and I think they need to know that the folks that are acting locally have been properly briefed in terms of just how they ought to handle this situation.

Could you comment on that?

Dr. SCHUCHAT. Yes, I can comment on that. We have issued community recommendations about things such as school closures and the gatherings that are associated with schools, as well as other large gatherings in a community. And what I think is important to say is that we have issued guidance that we think is prudent, that is relatively aggressive, but that recognizes the role of local authorities to modify based on the circumstances on the ground. We want to make sure every community has good information, but some of the local and State officials have even better information. So we are pushing this out to make sure everyone has guidance, but that it recognizes the local people may want to do more or even less than what we said.

Senator VOINOVICH. Does the communication, Ms. Napolitano, go to the governors and then down through to the counties? Because usually in our State, the county health officials and the city health officials are the folks that are on the ground?

Secretary NAPOLITANO. Senator, it is both. It is moving communication out to local public health officials and communication with governors and the like. So we are trying to get as much out to the relevant decisionmakers as possible.

Senator VOINOVICH. We have talked about the antiviral. The purpose of that is that somebody has the virus, and the antiviral deals with it so they do not get sick and die. The other part of this is the issue of vaccines, and millions of Americans have taken flu shots, including George and Janet Voinovich, my wife and I. And I think that you need to clarify that because you have flu shots does not necessarily mean that you are going to be exempt from this. Is that correct?

Dr. SCHUCHAT. That is right. It is great that you have gotten your flu shot, and I got mine as well. But that protects against the regular flu, the seasonal flu, not against this new virus, this new H1N1 strain.

Senator VOINOVICH. When are you going to be able to tell whether or not folks should be vaccinated for this? And, also, as somebody else, I guess, asked the question, how long do you think it would take to develop the vaccine? Is the CDC working with other world organizations so you can gather the best experts together to come up with this thing on an international basis?

Dr. SCHUCHAT. Yes, CDC has a role at the beginning in growing the virus strain and then handing it off to partners to make the product. We are working collaboratively, both here across the U.S. Government, the FDA, the NIH, and BARDA is really quite important. And through the World Health Organization, we are involved in a global basis. CDC's influenza experts are part of WHO's committee that picks the seasonal flu virus strains each year and that would also, going forward, advise about a pandemic vaccine if we needed to make it. So that is happening.

In terms of the decision to vaccinate, I am glad that you separated the question of the decision to make a vaccine from the decision to vaccinate. Some people look back to 1976 when we had an outbreak of swine flu in New Jersey and, reviewing the government response to that, wonder whether there was enough deliberation in separating the two ideas. So what I can say is we are working aggressively to make sure that if we need to produce a vaccine, we will be able to, and it could be available as soon as September 1, 2009, if all went well; but that we also are separating that particular decision from a later decision about use of a vaccine in the fall or when the vaccine was available. And I think that the best scientific minds will be contributing to that decision.

Senator VOINOVICH. Right, because sometimes the vaccine in itself gets people sick, doesn't it?

Secretary NAPOLITANO. Senator, yes, and that decision, once there is a vaccine, about who to vaccinate and how to do it is not an easy one, and it will be informed by the best scientific advice we can get. I spent last night reading a book about what happened in 1976 with the decisionmaking on the last iteration of swine flu. So we can learn from past history in terms of what kind of decisionmaking process we need to go through.

Senator VOINOVICH. Have you decided yet in terms of who is most vulnerable, or is it across all ages? Is it that young people are

more vulnerable or the older people? Or is it just they are all about the same?

Dr. SCHUCHAT. The information so far suggests that we have not been seeing confirmed cases in older populations, but it is early. We have teams trying to get better information verified from Mexico, and here in the United States we are looking at the cases we have. Our cases have an average age that is quite young, in the 20s, or teens, not seniors. But we are also prepared to see changes, and so we are not able to say yet the highest risk group, but we are looking into that.

Senator VOINOVICH. Thank you.

Last but not least, I am Ranking Member on the Appropriations Committee's Homeland Security Subcommittee, and I understand you have enough money to take care of the situation now, but that you are going to be looking for money in the supplemental. Is that correct?

Secretary NAPOLITANO. Senator, the President announced yesterday he was going to seek \$1.5 billion, and I think that is a rough estimate, and it is gauged on perhaps having to purchase more antivirals.

Senator VOINOVICH. But you have enough money right now to hold it over because we do not know when that supplemental will be finally—

Secretary NAPOLITANO. Yes, sir.

Senator VOINOVICH. Thanks very much.

Chairman LIEBERMAN. Thank you, Senator Voinovich. Senator Pryor, good morning.

#### **OPENING STATEMENT OF SENATOR PRYOR**

Senator PRYOR. Thank you, Mr. Chairman. Thank you for doing this.

Let me start with you, Dr. Schuchat, and ask about this particular strain of flu. And it may be too early to know the answer to some of these questions, but there is a perception that it is worse in Mexico, more lethal in Mexico than it is in the United States. Is that a fair perception? Or do we know yet?

Dr. SCHUCHAT. The initial impression was that confirmed cases from Mexico were severe, hospitalized young adults with pneumonia. As the investigation in Mexico expands, apparently they are confirming illness in milder circumstances, and so I think we may yet find that truly they have a worse problem in terms of severity than we do, or that it may have just been the quality of the information early on in terms of where we were looking.

Senator PRYOR. I do not know how the process works in terms of you determining the mortality rate of a particular strain of flu virus. How long does that take you? And what factors do you consider?

Dr. SCHUCHAT. There has been a lot of planning around the severity index for a pandemic. Sort of like categories for hurricanes, we have been thinking of categories for pandemics, where a seasonal flu would be a Category 1, and a Category 5 pandemic would be a higher mortality situation.

We are in early days. We are looking at the illness that we see and calculating the proportion that is fatal. But until there is a

larger number of definite cases experienced, we cannot precisely say things.

I can say that we are acting aggressively, implementing these community guidance efforts to tamp down transmission, assuming that this is a serious situation that we can improve through reduced transmission at the community level.

Senator PRYOR. And I understand that the flu virus mutates. Is it, again, too early to know whether you are seeing the mutations in this virus?

Dr. SCHUCHAT. It is very important that we continue to learn, that we not make all of our response efforts based on the first few isolates of virus that we tested, because it is possible that the strain will change over time. It may become more severe or less severe. It may acquire resistance, which it does not have right now. So we are following it, and the laboratory scientists at CDC—24 hours a day we have shifts working on the specimens that we have, really doing a phenomenal job.

Senator PRYOR. Is the news media helping you in your efforts right now? I know there is almost wall-to-wall coverage on this, and there is a little bit of a media feeding frenzy. Is that helpful?

Dr. SCHUCHAT. One of the most important things during an outbreak such as this is clear, accurate, timely communication, and the media has a very important role to play. We are committed at CDC—and I know the Department of Homeland Security feels the same way—to be accessible, to get information out as we know it, and the media is our partner in that. So I appreciate the help that they have given us in making sure people know what is going on. I think they are getting tired of a few of our faces at this point, but we really do want to get our information out, and we need them.

Senator PRYOR. Good. Thank you.

Secretary Napolitano, it is good to see you again. Thank you for your public service. I know you are doing great things at DHS already, and now you have this pandemic, or at least this flu episode that you are dealing with. So thank you for your service.

Secretary NAPOLITANO. Thank you, Senator.

Senator PRYOR. Let me ask you about vaccines and antivirals. I am assuming that there has been a lot of preparation on how to distribute those around the country. One of the questions I have is for the States. When the States receive vaccines and other materials, should they use them on their population, or should they use them in a neighboring State that may have a worse situation?

Secretary NAPOLITANO. Well, there is a robust plan for how things like vaccine and antivirals are distributed through the public health community, and on this one, what we are doing is the first States that are getting the antivirals are the ones where we already have either confirmed cases of disease or along the southwest border. But we are moving things out very quickly, so by next week every State will have its proportionate share. And because this is a rapidly changing picture and every time we get a new report, there are more States that have either reported suspect cases or confirmed cases, every State then will get it distributed within its own boundaries, according to its own plan.

Senator PRYOR. And I know it is way too early to be putting together a lessons learned memo on this, but as early as we are in this process, are you already seeing areas where you know we can do better next time?

Secretary NAPOLITANO. Senator, it is awfully early. It has been less than a week that we have been at this, although we have been at it, it seems, 24 hours a day. But obviously we are keeping track of what we are doing, and there will always be lessons learned from an episode like this. There are going to be things at the end that we say we would do differently, but right now we are kind of in it.

Senator PRYOR. Well, you are both doing great work, and we appreciate you, and I think both of you, as well as Federal agencies generally, have done a very good job of keeping the public informed and giving realistic assessment of what is going on out there. We appreciate it. Thank you very much.

Secretary NAPOLITANO. Thank you.

Chairman LIEBERMAN. Thank you very much, Senator Pryor. Senator Burriss.

#### OPENING STATEMENT OF SENATOR BURRIS

Senator BURRIS. Thank you, Mr. Chairman. I want to add my thanks to these two distinguished public servants for their prior service and current service and, of course, being right in the middle of the firestorm. So you have our congratulations, and we want you all to keep up the good work.

Just prior to coming to the Committee, I was on the phone with my public health director from the State of Illinois, and we do have eight cases that now are suspect. They are now going through the testing process, and it is primarily in northern Illinois. So we can hope and pray that they are not, but I do not think it looks that promising.

Madam Secretary, I was just concerned about the challenges surrounding this flu and the treatment and the information and how you communicate. In the community of Chicago, we have about 30-plus languages that have to be spoken, and getting the word out in all those different languages will put a strain on the resources of the city and the State. And I just wondered if any of those dollars that the President has asked for would be some type of grant funds that could go to assist in the overall costs that the States and local governments would be experiencing during this situation.

Secretary NAPOLITANO. Senator, I think that the initial request from the President is rather general, and we are working now on how to sculpt it to be best used as we go through this epidemic. So that will be one of the ideas that we will take back.

Senator BURRIS. Please do because budgets are already in bad shape in the cities and State government. I know mine are operating at major deficits, and these types of crises bring additional responsibilities and expenses that have not been budgeted for, which means you have to rob Peter again and you will not be able to get it from Paul because Paul does not have anything either. So keep that in mind that we are going to need some assistance as we try to go through the financial part of this.

Secretary NAPOLITANO. Senator, as a former governor myself, I am very sensitive to the fiscal situation of the States and cities in the country. And what we want to make sure of is that resources are put in the best place to have the greatest impact. And, again, all our decisions are going to be based on science and an evaluation of what is the most efficacious way to protect the safety of the American people.

Senator BURRIS. I also agree with Senator Voinovich. I have been in contact with my pork producers in the great State of Illinois, and they are requesting that we come up with some other name for this influenza, this virus, because they call it "swine flu," but you always hear the reports saying it has nothing to do with swine. And so if that is the case, how do we come up with some other name for this? By the way, is it strain A? I thought it was strain A.

Dr. SCHUCHAT. Right, this is influenza A, H1N1, and for the time being we are calling it 2009 H1N1 influenza.

Senator BURRIS. That is not sexy.

Dr. SCHUCHAT. It really is not catchy, no. But I think I said before you were here that there is no evidence that eating pork or pork products is associated with this condition, and we think that is an important message to get out, that this is not something that you get by eating pork.

Senator BURRIS. But has it gotten so in the system that you cannot back it off and come up with some immediate terminology? Because our pork producers are really concerned that people are going to stop buying it. And you hear when Japan and some other countries have stopped—I think it was China that said they are not taking any American exports of pork. Madam Secretary, is there any type of name we can—I know you are not the medical one. Put on your legal hat. You were also an Attorney General, right?

Secretary NAPOLITANO. Yes, I have had many jobs. And in my written testimony for this hearing, I just call it "H1N1," and actually, once you say "H1N1" a few times, it does roll off the tongue. But I know I was with the Secretary of the Agriculture and the U.S. Trade Representative yesterday, and we were talking about our coordinated and joint efforts to get the word out that this is not a pork-borne illness and that you cannot get it by eating pork. But I think we need to continually send out that message, and I know the Secretary of Agriculture is dealing with some countries that are using this as a purported reason to restrict imports.

Senator BURRIS. I want to thank you all. I think that is the end of my questions. Thank you all very much.

Thank you, Mr. Chairman.

Chairman LIEBERMAN. Thank you, Senator Burris. Senator Graham, good morning.

#### OPENING STATEMENT OF SENATOR GRAHAM

Senator GRAHAM. Good morning, sir. Can you get this from eating pork? [Laughter.]

Secretary NAPOLITANO. No.

Senator GRAHAM. OK. Making sure we are on message here.

The opportunity to deal with this problem in terms of creating a vaccine—maybe by September. Is that right, Dr. Schuchat? Do

we have the legal protections in place that would encourage the pharmaceutical companies to develop a vaccine that fast without being sued for trying?

Secretary NAPOLITANO. Well, Senator, there are several protections in place. There is the Public Readiness and Emergency Preparedness Act at 42 U.S.C. 247d, and you might examine that. But that is a statute that is guided by the Secretary of HHS, but designed to provide that sort of protection. That is one of the things in place now.

Senator GRAHAM. Well, from my point of view—and I would assume that most of the Committee would share this—if we are going to embark on such a bold project, which it seems like it would be smart to do, we need to make sure we have the laws in place that think through what happens to those who try to help solve this problem. So as you go back and inventory the legal environment, if you find gaps or you think you need it to be beefed up in terms of providing liability protection for those to help us with this problem, please let this Committee or the appropriate committees know.

Now, let us talk about the worst-case scenario for a moment, hoping it never happens, but let us just put it on the table. I guess the worst-case scenario would be that in the fall this thing spreads, that you have to consider closing the border with Mexico. Would that be one of the worst-case scenarios?

Dr. SCHUCHAT. I would like to clarify my previous remarks when we were speaking about closing the border. Going forward, there is no circumstance in which I think border closure might have value. It was a question of if we had no cases here and the first case was someplace far away, a border intervention makes sense.

Senator GRAHAM. Well, let us talk about that. Let us say that we have more cases here, but we have a vaccine that works, but they do not have one in Mexico that is not working, and they keep having more cases. We are controlling the ones we have. Why wouldn't you want to consider closing the border there?

Dr. SCHUCHAT. Just a few comments. I think that populations that have extensive disease are likely to be protected going forward. Mexico may be in the best place going forward because this thing may have already run through their communities.

Senator GRAHAM. Do you think that has happened in Mexico, that it has run through—

Dr. SCHUCHAT. No, I am just saying that if we are talking about 6 months from now when a vaccine might be available. But this is really a global issue and a global problem with global solutions, and the World Health Organization has been focusing on the international vaccine questions and development and deployment. For us, we expect if we went ahead and made vaccine, it would be available by the fall.

Senator GRAHAM. Well, Madam Secretary, if I may be so bold, I could foresee a scenario where Mexico or Canada—one of our neighbors that this problem could get worse while it is getting better here, that you would have to take some pretty drastic action. Do you have a plan in such a situation? Is there any contemplation by the Administration of a plan that would indeed seal the border if it was required?

Secretary NAPOLITANO. We have plans for a number of different contingencies and scenarios, but I will tell you, Senator, this situation really changes daily.

Senator GRAHAM. Right.

Secretary NAPOLITANO. So we will make decisions informed by science and what we think makes sense under—

Senator GRAHAM. Yes. I am not suggesting that you need to do that and hope we never will. I am just suggesting a lot of criticism about Iraq is you always assume the best and never plan for the worst. Let us not repeat that.

We have guest worker programs—I think Senator Chambliss mentioned it to you yesterday—where we get a lot of labor in the agriculture community coming from Mexico and the H-2A and H-2B visa program, and the farmers need the labor. Where do we stand in terms of making sure that legal immigrant population that is coming in to work here during the summer and the fall—what are we doing about that problem when we are going to bring a lot of people from Mexico here to work in agriculture?

Secretary NAPOLITANO. Senator, we really are handling the H-2A population the way we are handling travelers in general; that is to say, they are monitored to see if they have any signs of disease, asked if they have any signs of disease, and handled in that fashion. But, otherwise, they are legal travelers because they have visas. So they would come in.

Senator GRAHAM. Are you doing anything new for that population beyond just what you do at the border for somebody driving a car through?

Secretary NAPOLITANO. Not currently.

Senator GRAHAM. Do you think it would be wise to look at doing something new?

Secretary NAPOLITANO. Yes.

Senator GRAHAM. That is fair. Now, if we have to administer immunization to the population as a whole—is that a remote possibility, Dr. Schuchat, in a worst-case scenario event?

Dr. SCHUCHAT. These are early days to know whether that is the type of step we would take. One of the things we try to do in this stage is learn as much as we can about who is getting sick and who is not, and that can inform who might—

Senator GRAHAM. Can you see any reasonable possibility down the road based on science where that might be required?

Dr. SCHUCHAT. Yes, absolutely. There is a reasonable possibility.

Senator GRAHAM. And you are planning for that, I take it.

Dr. SCHUCHAT. Absolutely. That is why the past several years we have been investing in better manufacturing capacity and new technologies and so forth. So certainly the planning cases have been whole population, two doses.

Senator GRAHAM. All right. Now, while we have some legal protections for companies that would help develop the vaccine—you have talked about that, Madam Secretary. Look and see if you need more. What about the people who would administer the vaccine? What about the health care professionals that would be tasked under the worst-case scenario to go out and administer this drug to the population as a whole? Do we have any liability protection for them on the books?

Dr. SCHUCHAT. I am going to need to get back with you about that. I am not aware that is a concern. I think the primary one had been about the manufacturers. Remember that if vaccine is delivered in this context, it would be under the Federal Government's authority.

Senator GRAHAM. The only reason I mention that, being a military lawyer, is we have a requirement you get vaccinated for certain problems in the military, and we had a problem with anthrax, and we had mandatory vaccinations, and we had a few cases of people that react. Well, they do not have the choice in the military because you are part of the military, that is your job. But if we do go to a mandatory immunization to the population as a whole like we have done in the past, I think we need to really think about what exposure the health care professionals have and do something about it now while we have the time.

Thank you both. I think you have done a good job. And the only reason I am talking about this is if it gets better that is great. If it gets worse, that is not so great. And I can understand how hard this is, but we have guest workers coming in through a legal system. We have legal liability that is there, I think, in a limited way, and we need to look robustly at the guest worker program, a worst-case scenario to seal the border if you had to, and certainly to look at legal protections for those who are going to produce the vaccine and administer it, so that if that worst-case situation ever happens, we will not be behind the eight ball.

Secretary NAPOLITANO. Senator, thank you, and I think you are right that we have to be planning for the worst and hoping for the best. The statute that I referred to does include distributors, program planners, persons who prescribe, administer, or dispense.

Senator GRAHAM. Great. If you could send me a little memo about how detailed that is, what kind of liability protections, I would like to talk with you about making sure that is enough and improving it if we have to. Thank you.

Chairman LIEBERMAN. Thanks very much, Senator Graham.

Secretary I appreciate your answer to Senator Graham's conditional question about whether you would be open to considering increasing the checks on people coming in from Mexico—guest workers, for instance—with regard to their health, because I think if you do not, there will be growing pressure to really close the ports of entry. And I understand it is complicated with the number—the volume is what, 800,000 to a million a day coming across? Does that sound right?

Secretary NAPOLITANO. I will double check. It is an awful lot.

Chairman LIEBERMAN. It is an awful lot of people. So the thought—because, really, in our minds what we would like to think is that everybody would be stopped, and you would take their temperature. You would look at them to see if they are coughing or sweating or whatever. And the Mexicans would have the right to do that to people going in, if they wanted. So how we go from where we are now, which frankly does not sound like much—and I know how hard it is—to something that will create a slightly more demanding screen for people coming in is, I think, very important to think about, or I believe the pressure will grow to do

something much more definitive, like closing some of the ports of entry.

Secretary NAPOLITANO. Mr. Chairman, I agree, if we go to an enhanced closing the ports or enhanced every individual gets screened protocol, we are going to have to be able to explain because that will cause delays and lines in processing. What is the advantage we are getting from that other than symbolism in terms of actually preventing disease in our country? And right now what the scientists are telling me is, beyond symbolism, we really do not get an advantage in terms of spread of disease. But if we go that far, we are continually thinking and rethinking this. That is really the explanation we are going to have to be prepared to give.

Chairman LIEBERMAN. Yes, this is a classic of the very hard decisions when you are balancing factors. Obviously, you have to listen to the science. And, again, common sense would say if we are trying to stop people from congregating places, which they are doing in Mexico already—and, of course, it is starting in places here; a couple of schools are closed in Connecticut today because of suspected cases—then there is a natural next step to say, well, maybe we should then try to stop mixing of people coming over the border for the same reason.

So you have got to weigh what is the public health benefit from that. How much does it cost you to implement such a system? And then what are the economic consequences and personal consequences on our country and our neighbors in Mexico? These are not easy decisions. But if it spreads, I think we are going to be faced with those questions, and I think what you are hearing today from Members of the Committee is what we are not only thinking but hearing from our constituents. And I think those calls will grow louder, and you understand that.

I want to go to another subject. Talk about tough decisions to make. I wanted to ask about both the antivirals and the vaccines. Here is a basic sort of uninformed patient's question about the medical consequences. Am I correct in assuming that in the case of the infant that died in Texas today, the confirmed death from swine flu, and the almost 150 people, maybe more now, in Mexico that have died, that was because they were not administered a course of the antiviral? In other words, why do some people, apart from their own vulnerability—and maybe that is it. Why do some people die from this and others seem to get it and go on?

Dr. SCHUCHAT. Influenza is a virus that can cause severe disease, even the seasonal flu. So each year in the United States, about 20,000 young children are hospitalized from flu and between 50 and 150 do die with just regular seasonal flu.

I do not have the specific circumstances of the child in terms of treatment. We know that antiviral drugs can improve the response, but people may die with or without them. But we do think antiviral drugs are effective at reducing the risk of bad complications.

Chairman LIEBERMAN. That helps me to understand it. So if we hear that people are dying from the swine flu, it is a result both of their own vulnerability and perhaps—although this would be the rare or unusual circumstance—the antiviral, if they got it, just did not work. Or it was administered too late, for instance.

Dr. SCHUCHAT. Yes, all of those circumstances are possible.

Chairman LIEBERMAN. But the probability is if you get the antiviral treatment, once you have been confirmed, you are going to get better.

Dr. SCHUCHAT. The prompt treatment increases that probability, but for vulnerable hosts, sometimes the medicines are not enough, and babies are among those at greatest risk for seasonal flu.

Chairman LIEBERMAN. So one of the judgments that you are making, I assume, is how many more of the antiviral courses do we need? We have 50 million. We are giving out a quarter of them now. Am I right, you are trying to make some projection and then go ahead and purchase them with part of this \$1.5 billion the President has asked for?

Dr. SCHUCHAT. Yes, that is right. We are looking into what we have on hand and what we may need going out. When we made the original estimates of how much to procure in the Strategic National Stockpile, it was really forward thinking in a supply-limited environment. If we have time now to produce more for the years ahead, there may be some benefit in that, but it is being looked at.

Chairman LIEBERMAN. So now let me go to the vaccine. Am I correct that a decision has been made that if we can develop a vaccine for swine flu, we will definitely make it?

Dr. SCHUCHAT. I do not believe that decision has been made yet. What has been made is that we are taking all the steps necessary, if we decide to make a vaccine, to make one. So we have the seed strain being looked at both with the traditional egg-based cultures and then also with this reverse genetics approach. We have the industry lined up to be partnering with the government. We have NIH ready to do the clinical trials that would be needed. But there is this phase before you actually go to large-scale production, which will define whether or not you are going to, and which kind of vaccine you should make.

Chairman LIEBERMAN. If you all with your extraordinary capabilities develop a vaccine that works against swine flu, why would we not make it?

Dr. SCHUCHAT. First off, CDC does not actually make the vaccine. We are just one part of the family—

Chairman LIEBERMAN. Understood. But you know what I am saying. I am asking a public policy question. I assume if we could develop it, we would make it.

Dr. SCHUCHAT. Well, I think we will be learning quite a bit about what it is going to take to make one in terms of—we were disappointed originally with the H5N1 vaccine products. You needed a huge amount of antigen in order to get a response. If you added an adjuvant component, you did not need so much. There is a lot of science that will be going on in the next few weeks or months that will help us understand what we could expect, how much could we make, how much response might it give.

Some of the influenza virus strains do not grow that well, and it is hard to make a vaccine from them. So we do not know.

Chairman LIEBERMAN. Secretary, do you want to weigh in on this? Because I would assume that if we can make it, we will.

Secretary NAPOLITANO. Well, these are obviously—exactly. And, again, I want to just say these decisions need to be informed by science.

Chairman LIEBERMAN. Right.

Secretary NAPOLITANO. But vaccines are not in and of themselves benign, and so they can themselves cause a certain amount of illness and mortality in the population at large. And so one of the things that you need to look at is what is the overall benefit of a large-scale vaccine program in terms of the severity of this H1N1 virus versus what you might get from a vaccine. So that just illustrates for you, I think, Mr. Chairman, that there are a lot of factors that need to be taken into account.

Chairman LIEBERMAN. I assume that if we decided to produce a vaccine because we found one that worked on swine flu, the aim here would be to produce 300 million doses so that we could at least have the capacity to administer one to every American?

Dr. SCHUCHAT. The planning that was done was with that in mind, and including who would be among the first to get such a vaccine, critical infrastructure, and some other groups.

Chairman LIEBERMAN. Talk about hard judgments to make.

Dr. SCHUCHAT. Yes, and we actually did both expert group input and also public engagement about what did people value the most, those who were most likely to die from an illness, those who would keep society going. We got very good input from a series of public engagement efforts about that in our planning a couple years ago.

Chairman LIEBERMAN. Do we have the domestic capacity to produce sufficient quantities of vaccine up to the 300 million?

Dr. SCHUCHAT. The investments in pandemic preparedness that Congress made possible have resulted in phenomenal expansion in manufacturing capacity so that we are very optimistic going forward about what we can expect. But this virus can surprise us, and even with all those investments, it may just technically be difficult.

Chairman LIEBERMAN. Thank you very much. Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Doctor, I want to talk further with you about the vaccine issue because the 1976 experience is a real cautionary tale, and I know that Secretary Napolitano was saying that she was reading a book about it, and I have refreshed my memory about it as well.

In this case, it turns out that health experts were mistaken about the kind of flu—it turned out to be an avian flu, not a swine flu—and the CDC Director had urged the President and Congress to undertake a mass inoculation program of the population. And within a few months, almost 25 percent of the population had received the vaccine, but it was not a very happy result. It turned out that the vaccine had serious consequences for some individuals, producing a rare neurological disease. Five hundred people contracted the disease as a side effect of the vaccine; 25 of them died.

What have we learned from that terrible experience? It really was a debacle. It caused the head of the CDC at the time his job. What have we learned from that experience in 1976 that we can apply to the situation today?

The reason I ask this is for those who were not around in 1976 or who are too young to remember what happened, there is a tendency to see the vaccine as the magic answer, as the solution.

Could you talk to us about what lessons CDC has learned that would prevent a reoccurrence of what happened in 1976?

Dr. SCHUCHAT. Thanks for that question. I think that it is humbling going forward to look at the complexity of decisionmaking that will be necessary, and I think an important lesson to be learned is how important careful deliberation, best case and worst case scenarios, looking really at all sides of an issue, will be needed—the health benefits, the health risks, the social benefits and social risks, the economic issues.

I think that we hope to have—CDC is just part of the story, of course, but I think we really hope to be able to step back and make decisions carefully amongst the affected groups and to seek wise counsel from dissenting views, to really get people to look at things from a different perspective.

I can mention that CDC pretty much routinely, for our emergency responses and also for this one, has a Team B, a group that is really not involved in the response but stepping back and looking at it and trying to think about issues where we really might not be going on the right track or where other perspectives might be very useful.

I think Secretary Napolitano might have some other ideas since you refreshed your memory last night.

Senator COLLINS. Secretary Napolitano.

Secretary NAPOLITANO. Well, I was a college freshman in 1976, so my memory was a little stretched. [Laughter.]

Senator COLLINS. It really bugs me when our witnesses are younger than I am, Mr. Chairman.

Secretary NAPOLITANO. But, yes, I think the doctor has it right. And what we want to do is make sure moving forward that we are getting lots of different inputs as we approach what can be some very difficult decisions where you are constantly weighing what is the benefit to be gained versus the cost. And it is not just the CDC, but other members of the academic and scientific community. It is members of the private sector who have to give us input about what would be the economic impacts of some of our decisions. And it really has to be taking into account a myriad of different factors in terms of whether you do a universal vaccine program.

Senator COLLINS. That is the point that I wanted to make. It is not an easy decision to decide to do a mass inoculation, and while I am sure that the science behind vaccines has improved in the last 30 years, the experience of 1976 should cause us to proceed with caution. And I am confident that you will do that.

Madam Secretary, I want to turn back to the border issue that we discussed earlier. You took some issue with my description of the process that CBP is using when I described it as “passive surveillance,” and I think it is important for the record to note that is the term that the Department of Homeland Security is using, and, indeed, as recently as 2 days ago in a press update, the Department has said that the Customs and Border Protection has also implemented passive surveillance protocols.

Furthermore, in that same document, where there is a frequently asked questions part, when the question was asked, “What steps are you taking to prevent those with flu-like symptoms from crossing the border?” The response is not very reassuring to me and, indeed, to many other Members, because the response is, “As part of CBP’s routine procedures, if someone is crossing the border appears

ill, the person is referred to a quarantine station or a local public health official.”

We should be going beyond routine procedures given the threat.

Secretary NAPOLITANO. Senator, first of all, I think your point is well taken. We have used the phrase “passive surveillance.” But we have also used the phrase “swine flu.” As we go through this over these days, we are determining better ways and more precise ways to communicate. So “passive” seems to suggest that nobody is doing anything, and the answer is they are following a direct protocol to examine, to look, to ask questions.

And when they say “routine,” what they mean to say—what that is is that, for example, we are constantly at the border trying to check to see whether individuals who may have tuberculosis are crossing the border as a problem within Mexico, so that if you see somebody present who has signs of illness, coughing and the like, they have a travel history in Mexico, particularly certain States within Mexico, they can be isolated in a room and examined further, that is the routine. But that is virtually identical to how we are dealing with identifying those who may have flu.

Senator COLLINS. Well, let me tell you why I am so concerned. In 2007, our Committee did an investigation of the case of the Mexican citizen who crossed 21 times back and forth across the border, despite the fact that CDC had identified him as having a highly contagious, drug-resistant strain of tuberculosis. So here is an individual who has been identified by CDC, and yet Customs and Border Protection was still unable to stop him from crossing almost two dozen times.

Now, I have a great deal of respect for how hard the Customs and Border Protection officials are working. I also know that they are very well meaning and that they are well trained. But if they cannot catch an individual who has been specifically identified as being a public health threat, whose name they actually have, then why should I have any confidence that they are going to be able, using just what are described as “passive surveillance” protocols, not using electronic scanners or other technology, why should I have confidence that they are going to be able to screen for this serious flu, particularly since, as the Chairman mentions, the volume of people crossing every day is just enormous?

Secretary NAPOLITANO. Senator, I think the question you raise is the same question in a way that Senator Graham was raising: Are there some things that we can do with respect to visa issuance and the like that will diminish the possibility of somebody carrying flu coming over? And we are open to those ideas and suggestions. But, again, the decision to actually close the entire border, which is what has been raised—and since we have flu in Canada, I would anticipate that the same argument would be made there. So closing both borders, with all of the huge impacts that would have, in light of the fact that the scientists and the epidemiologists say would have virtually no impact on the amount of disease in our country, when you balance those things, particularly in light, as you say, of the difficulty of knowing whether any individual has disease, and when you make that whole package of decisions, you understand why closing the border is not an adequate answer to this epidemic.

Senator COLLINS. I realize my time has long since expired, but let me just make very clear: I am not advocating closing the border. That is not my position. The only time that would make sense to me based on the expert testimony we have had today is if you temporarily close the border in order to allow the distribution of medicine to key areas or perhaps the vaccination of Customs and Border Protection officials at the border. Then it might make sense to close it for a brief time to allow that to occur. So that is not what I am advocating.

I am advocating for a stepped-up medical presence at the borders. I am advocating for the use of technology, perhaps these scanners that six other countries are using. Even if they are not perfect, they are going to catch some of the cases. And I am advocating for enhanced, active questioning surveillance techniques.

So I just want to clarify that I think there are steps that can be taken between what we are doing now, which I do not consider to be adequate, versus closing the border. There are more effective enhanced methods that could be put in place, and I just urge you to consider them, which you have already indicated you are willing to do.

Secretary NAPOLITANO. Absolutely.

Senator COLLINS. And, again, I do want to applaud you for the response. I have talked to bioterrorism experts who say that we are doing so much better a job. And as the doctor has made clear, our preparedness has grown by leaps and bounds due to the investments that Congress has made, and effective leadership. So I thank you for that.

Secretary NAPOLITANO. Thank you, Senator.

Chairman LIEBERMAN. Thanks, Senator Collins.

I echo Senator Collins. I was thinking here at the end, naturally, we—Members of the Committee, myself included—pushed you on some of the tough questions that are in some sense ahead. That is the nature of what we are thinking about and what people are asking us. But I do not want that to diminish our feelings—again, I speak for myself here—that this was one of those cases where the Federal Government is prepared, that we have a plan, that we have a Department that is relatively new but that coordinates quite a wide array of the agencies that are directly involved here, and in cases where it does not have all that direct expertise, it works very closely obviously under your incident management position, Secretary Napolitano, with groups like CDC and now Secretary Sebelius at HHS.

So I think there is a lot of reason for the American people to feel encouraged that the Federal Government is really there on this occasion protecting them. I think you have heard—obviously the President has indicated this by his request for \$1.5 billion—from Senator Voinovich, Ranking Member on the Appropriations Homeland Security Subcommittee, that there is going to be no resistance here to providing you and the other departments of our government with all the money you need to protect the American people from the spread of this disease, which we are rightly taking seriously.

So I appreciate everything you have done. We are going to, as a Committee, stay involved in this. I cannot help but express a certain amount of not only gratitude to you, Secretary Napolitano, but

pride since this is the Committee from which the Department originated, and I think you have shown us thus far in this crisis why it was a good idea to form it, not just in response to September 11, 2001, but to help our government better manage a host of other emergencies, including this kind of public health emergency.

So we are going to keep the record of the hearing open. I suppose I should ask each of you—it is a bit unusual—whether you have anything you would like to say in closing.

Dr. SCHUCHAT. Just that we really appreciate the support that Congress has had for preparedness in the past and to help us with the situation now.

Chairman LIEBERMAN. Thank you.

Secretary NAPOLITANO. I echo that, but also to say that communication here is going to be so important. This is an evolving situation. I was just handed a note that they now have 13 confirmed cases in Canada, which I was not able to answer earlier. So every half-hour or hour we get a different picture, and my goal is to communicate with the Committee, with the Congress, what we are doing, why we are making decisions as we make them, and to communicate the same with the American people.

Chairman LIEBERMAN. It is very important. We appreciate it a lot. Thank you.

The record will stay open for 15 days for additional questions and statements as desired. For now, that is it for this morning. Thanks for your time.

The hearing is adjourned.

[Whereupon, at 12:12 p.m., the Committee was adjourned.]



## H1N1 FLU: PROTECTING OUR COMMUNITY

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MONDAY, SEPTEMBER 21, 2009

U.S. SENATE,  
COMMITTEE ON HOMELAND SECURITY AND  
GOVERNMENTAL AFFAIRS,  
*Hartford, CT.*

The Committee met, pursuant to notice, at 10 a.m., at the Legislative Office Building, Hearing Room 2E, 300 Capitol Avenue, Hartford, Connecticut, Hon. Joseph I. Lieberman, Chairman of the Committee, presiding.

Present: Senator Lieberman.

### OPENING STATEMENT OF SENATOR LIEBERMAN

Chairman LIEBERMAN. I thank everybody for being here, and I particularly thank the witnesses. I particularly want to thank my wife, Hadassah, because I rarely have the opportunity to say that. She is in attendance today. This speaks to the fact that, like everybody else, she is concerned about the topic of this hearing, which is the extent to which we are prepared to deal with an outbreak of H1N1, what we used to call swine flu, and a lot of people still do.

This is a field hearing of the Senate Homeland Security and Governmental Affairs Committee. We want to particularly look at Connecticut's preparedness for a resurgence this year of H1N1 influenza. Some might ask why the Committee on Homeland Security and Governmental Affairs is interested in this.

The Committee on Homeland Security and Governmental Affairs was created after September 11, 2001, to organize various agencies of our government to do everything we could to make sure that there were no gaps, there was no lack of communication, so that the vulnerabilities that the terrorists exploited on September 11, 2001, would not be there—to the best of our ability—in the future, but it was also put together to make sure that in a coordinated way we could deal with natural disasters. The Federal Emergency Management Agency (FEMA), for instance, is in the Department of Homeland Security now.

The Department of Homeland Security (DHS) is designated under Executive Order as the Department that manages incidents of national significance. And the President has declared this to be an incident of national significance, so Secretary Janet Napolitano at the Department of Homeland Security is the lead Federal coordinator of our response, even though you see Secretary Kathleen Sebelius of the Department of Health and Human Services (HHS) a lot, which is quite understandable because of the nature of this.

I would also say that one of the things that I have worried about in this post-September 11, 2001, age is when we were told by the 9/11 Commission that one of the reasons September 11, 2001, happened was because of a failure of imagination. And what did they mean by a failure of imagination? The failure to imagine that people would actually do what was done to us on September 11, 2001.

So we spend time—it is not the most pleasant way to spend time—trying to imagine what others might do to do damage to us. We just had a report come out from the Commission that said that in terms of fear of terrorists using a weapon of mass destruction, that the most likely weapon would not be everybody's nightmare scenario of a nuclear weapon, but it would probably be a biological attack because of the relative ease of taking pathogens and making them into biological weapons.

So, obviously, there is a lot that our intelligence community and others, Customs and Border Patrol (CBP), the Transportation Security Administration (TSA), a whole range of others, will do to try to prevent such an awful thing from happening to our country. But then part of what will be on the line, which will determine the extent to which, God forbid, such an attack ever happened, we can both limit its impact and treat those who have been affected by it involves much the same kind of work we are doing with our public health system and with communications to the public to limit the spread of H1N1.

So in those ways, this hearing falls both directly into the Homeland Security Committee and relates to the antiterrorist work that the Homeland Security Department and our Committee does.

Again, I want to thank the witnesses who are here today. They represent a broad range of experts in the field, people with responsibility. And they will help us determine what the nature of this flu is now, what the potential is during this flu season, and what we all can do together to inhibit the spread.

We are obviously holding this hearing now because we are at the beginning of the flu season, but September also happens to be National Preparedness Month, and it therefore gives me an occasion because National Preparedness Month is about what each of us can do to secure our country.

Each of us can contribute in our own communities to inhibiting the spread of flu by the way we conduct ourselves, things as simple as washing our hands and covering our mouths, not with our hands but with our elbows when we sneeze, for instance. The point is that preventing the spread of the flu is actually something that every individual can and I hope will help with, and this hearing I am hopeful will help to spread that message.

H1N1, as we learned last spring, is a fast spreading disease. It was just detected last spring. It reached pandemic proportions, worldwide, over the summer, and appears to be making a comeback as the traditional flu season begins.

The Centers for Disease Control and Prevention (CDC) estimated a few months ago that a million people in the United States had become ill with this flu, and they could imagine that millions more likely had been exposed to it since then. We know that 9,000 have been hospitalized in our country from the flu; that 593 have died from flu-related symptoms. Here in Connecticut, about 2,000 cases

have been confirmed, and by the records, I have seen that nine people have died from flu-related symptoms.

I would say that unlike other crises of this kind that we face, fortunately pandemic flu is one, through various means, that we have planned for and I think are better prepared for, but not as well as we should be.

In response to global outbreaks in recent years of avian flu, West Nile virus, and severe acute respiratory syndrome (SARS), the CDC developed a strategy for a coordinated national response to infectious diseases. The Homeland Security Council adopted a national strategy for how to respond to pandemic influenza. And with support from the Department of Health and Human Services and the DHS in Washington, our States, including Connecticut, have both been encouraged, pushed, and enabled to develop plans for addressing pandemic flu.

Following the spring outbreak, the medical and pharmaceutical communities have had time to study the H1N1 virus and, I think with remarkable speed, to begin to produce a vaccine; in other words, a vaccine to a flu that we just learned about last spring. That is the kind of world in which we live.

I never got to meet my paternal grandmother because she died in the flu epidemic of 1918 in New York. Obviously, there was not this extraordinary ability we have today to isolate a flu, to figure out how to develop a vaccine to it, and here it is now. Agencies at all levels of government have gotten advance warning that they need to be prepared for the possibility of a more severe strain of the virus this fall, even though today, thankfully, that has not happened.

So today, I am going to ask our witnesses representing State and Federal agencies what their H1N1 response plans are and whether they are working together or is there anything else we, at the Federal level, can do to address this challenge. I am going to ask our witnesses on the second panel from public educational institutions and businesses if the government planning has been constructive to them and what, if anything else, they are doing and they think we might do.

The good news to report today, perhaps it has already been known, is that the Federal Government apparently can begin delivery of the H1N1 vaccine to States as early as the week after next. Connecticut is expected to receive approximately a half a million doses by mid-October, which will be distributed first to those that public health officials believe are most at risk. That would include pregnant women, young children, daycare workers, health care and emergency medical personnel, and those with certain health conditions that make them more vulnerable to the flu, such as diabetes or immune deficiencies. The Federal Government is also providing money to States to help prepare for the fall flu season and to administer the vaccine. The Connecticut share of that will be about \$4 million.

At this point, the State appears to me—but I want to hear from you today—on track to stay out in front of a broad H1N1 outbreak. The truth is that we are very fortunate that, thus far, most cases of the virus have continued to show the same mild to moderate symptoms as we observed last spring, but outbreaks of infectious

diseases are very hard to predict. That is, the course infectious diseases follow is very hard to predict. So circumstances could still change significantly to become more serious over the coming months. And look, let's just be specific; nine people have already died in Connecticut from H1N1-related disease. So this was not, of course, a mild or moderate disease for them or their families or friends.

Therefore, our responsibility is to stay on heightened alert, to continue to take preventive action to work together, to communicate effectively with the public. And, as always, while hoping for the best and at this moment being confident of the best, we also have to prepare our public health system for the worst, for real demands on it.

So I thank the witnesses. I hope in sum that we can get a clear sense of preparedness for this influenza pandemic here in Connecticut and to see what our Committee and the Congress can do to help in the months ahead.

That is my opening statement. I am now delighted to go to the first panel. I think we are going to keep you to 7 minutes. We probably will not eject you forcibly if you have to go over a moment or two to convey the message.

This is a very distinguished panel. The first is Admiral Michael Milner, who is the Regional Health Administrator, Region I of the U.S. Public Health Service of HHS.

Admiral Milner, thanks for coming to Hartford to be with us this morning.

**TESTIMONY OF REAR ADMIRAL MICHAEL R. MILNER,<sup>1</sup> U.S. PUBLIC HEALTH SERVICE, REGIONAL HEALTH ADMINISTRATOR, REGION I, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Admiral MILNER. Good morning, Chairman Lieberman, and your staff. I am Mike Milner, as you said. I am with the U.S. Department of Health and Human Services and the Regional Health Administrator in Boston for HHS.

I wanted to deviate just a second and tell you how much I know personally your involvement. The last time I spoke with you, sir, was coming off the USS *Iwo Jima* in New Orleans, and we were having a congressional delegation related to our response to Hurricane Katrina.

Chairman LIEBERMAN. Yes. We came right down after Hurricane Katrina.

Admiral MILNER. Yes, sir.

Chairman LIEBERMAN. And thank you for what you did. You are the heroes.

Admiral MILNER. I certainly appreciate your passion for this activity and appreciate the opportunity to be here today to share with you what our Federal Government has been doing, what our office has been doing, and what our Northeast States have been doing together, and specifically partnering with our Connecticut colleagues to prepare for the pandemic 2009 H1N1 influenza.

<sup>1</sup>The prepared statement of Admiral Milner appears in the Appendix on page 197.

By way of background, I thought you should know briefly about my role and responsibilities with Health and Human Services as the Regional Health Administrator and how I came to be before you today. I have served as the senior Federal public health official for the six New England States since August 2003 and report to the Assistant Secretary for Health, Dr. Howard Koh.

Additionally, I serve as the senior Federal health official for both Regions I and II, HHS, as the health official for the regional coordination team as part of the Department of Homeland Security. You know that used to be called the Principal Federal Official Regional Program.

You have already stated broadly the outbreak related to the 2009 H1N1. It has triggered a worldwide pandemic and it is currently the dominant flu strain in the southern hemisphere as it is making its way north. The evidence to date shows that the virus has not changed to become more deadly. Unlike our typical flu season, we continue to see flu activity in the United States, and over the summer, of course, we had a lot of outbreaks in our summer camps here in New England. More recently, we have seen an increase in the activity in States in the Southeast and beginning to get reports of increasing numbers of cases here in New England.

As the fall comes, we anticipate that our communities will see more viral transmission, and we are preparing for that. This particular virus will be difficult to distinguish between seasonal flu and H1N1, which adds some complexity for us, and we are working together to both message and do the outreach and clinical care that will be needed.

Chairman LIEBERMAN. Let me interrupt and we will not run the clock on you. But just as a matter—I know people ask me this.

How does somebody know if they have H1N1 as opposed to regular flu or seasonal flu or even just sort of a bad cold?

Admiral MILNER. Well, there are a series of symptoms that we associate with influenza that tend to be different from the allergy reactions, runny nose, and sneezing that would be associated with allergies. The clinical presentation—you have to think about what is happening in the community. And so when we know that there is an increase of a certain type of infectious disease in a community, our suspicion goes up.

We have chosen, I think, to limit the amount of testing that we do simply because of the fact that the H1N1 seems to have crowded out the seasonal flu in the southern hemisphere. And we recognize that were we to do clinical testing of every one that comes into an emergency room (ER) or into primary care office, it would just completely overwhelm our laboratory capacity.

Chairman LIEBERMAN. In other words, based on what has happened south of us, where the H1N1 has dominated—I mean, it is much more frequent than the regular seasonal flu—we are reaching a judgment that if you show certain symptoms—

Admiral MILNER. We will make an assumption clinically that you have this particular strain.

Chairman LIEBERMAN. And begin to treat with antivirals.

Admiral MILNER. Correct. That prompts your clinical decision-making surrounding the care of that particular patient.

Chairman LIEBERMAN. I have heard different answers to this. Maybe there is not a single answer, but are there any symptoms that are particularly characteristic of the H1N1 virus or the flu?

Admiral MILNER. Dr. Carter is our resident epidemiologist, for infectious diseases.

Dr. CARTTER. Good morning, Senator.

Chairman LIEBERMAN. Good morning, Doctor.

Dr. CARTTER. A lot of folks keep asking, well, is it just the flu? And my response to that is it is and it is not. I mean, for the vast majority of us, H1N1 is going to feel just like seasonal flu; sudden onset of fever, headache, cough, muscle aches. And you are going to be sick for about a week and feel like you have been run over by a truck. So it is clearly much different than the common cold.

But there is no defining feature. What is interesting in this particular pandemic is that many of the younger people, children, also have gastrointestinal symptoms, and they have nausea, diarrhea. And this is a bit different thing than what we sometimes see with seasonal flu.

Chairman LIEBERMAN. Yes. Anybody else want to add anything? If not, go ahead, Admiral.

Admiral MILNER. Thank you. I am going to try to streamline things a bit.

Chairman LIEBERMAN. No. Do not be rushed.

Admiral MILNER. I think that the important thing from my perspective is that the Northeast States, the health officials, the emergency managers, communication directors, public health and preparedness directors, and a real array of Federal folks—we have CDC project officers, FEMA and Department of Defense planners, our Assistant Secretary for Preparedness and Response; we have emergency coordinators. All of us are working together, Homeland Security and HHS.

We have been engaged in very aggressive, detailed pandemic planning now for a number of years, and we have done it through face-to-face meetings. We have done it through active listening with our stakeholders, the communities we represent, the hospitals, the physician groups, the business sector, and our critical infrastructure sector. We have listened to their needs and tried to identify things that we can do to meet their needs during this kind of response.

We have gone as far as hosting multi-day meetings here in New England where all of our folks come together. We had an executive communications exercise a few years ago which really expanded our awareness of our communication challenges. We had the first regional exercise in the Northeast that exercised our FEMA concept of operations in terms of how the Department of Homeland Security, HHS, and FEMA will operate together to support our States.

So from the Federal perspective, we feel like we have been ahead of the curve nationally. And I think all of those efforts have really centered around our communication strategies from a regional perspective, the interstate and interregional cooperation, and work to try to improve our understanding of the scientific guidance as it is being identified. And we are then applying it to certain things that we do and we implement in terms of mitigation.

We have tried to see what the ground truth is, and we had a good opportunity in the spring to really field test this. Beginning April 24, we started—every morning, I was on a conference call with our New England State health officers. We talked about the ground truth and what they were experiencing and how this virus seemed different from what we had been planning for.

In my perspective of this, in my discussions with colleagues around the country, I believe New England and the Northeast was the tip of the spear in terms of our response. We were able to at 7:30 in the morning talk about why school closure guidance was not making sense because of the challenges that it presented. And later in the morning, we had calls from CDC and we shared the ground truth, and later in the day, after that, the guidance begin to shift.

So I really applaud the work of Connecticut and our New England health officers because they really were sharing things that helped the Federal Government identify areas that we could improve and modify our guidance.

So I think the truth is that I have been blessed to be in New England, to work here and to live here. And my own personal feeling is if I were to live anywhere with this particular virus looking at us, I am glad I am in New England and glad I am in the Northeast.

The rest of my remarks include information about CDC and the money that has been provided for the State of Connecticut. The Assistant Secretary for Preparedness and Response asked for that bit of money. But I believe the specific relationships that we have in the Northeast, our States, the working relationship we have here is very strong, and I am very respectful and very happy that I have the opportunity to work with such a great group of public health and emergency management leaders here in New England.

I see this light blinking. It is creating nervousness, so I will thank you for what you have done on behalf of the—

Chairman LIEBERMAN. Thanks, Admiral Milner.

Admiral MILNER [continuing]. The Northeast, for all of the resources that you have provided here. I believe this group is excellent stewards of those resources, and I believe that we are on the leading edge of this response from a Federal perspective. Thank you.

Chairman LIEBERMAN. Thanks, Admiral Milner. That is very reassuring. I appreciate your testimony. I would just say for the record that your full statement, and that of all the other witnesses, will be printed in the official transcript of the hearing, and I will have some questions for you, based on the testimony you have given.

Second is Dr. Matthew L. Cartter, State Epidemiologist working out of the State Department of Public Health.

Thanks for being here. It is good to see you again.

**TESTIMONY OF MATTHEW L. CARTTER,<sup>1</sup> M.D., STATE EPI-  
DEMOLOGIST, CONNECTICUT DEPARTMENT OF PUBLIC  
HEALTH**

Dr. CARTTER. Good morning, Senator. Thank you.

As you pointed out in your remarks earlier, H1N1 has been a particular interest of yours since the beginning, and I would like to thank you and the other members of our congressional delegation for visiting us here at the State Health Department in the spring. For those of us who are working on this issue, it has meant a lot to have you there, and we greatly appreciated that.

Chairman LIEBERMAN. Well, we learned a lot and we thank you.

Dr. CARTTER. I am here to give you an update on the current status of the influenza pandemic in Connecticut and the plans to distribute the newly licensed H1N1 vaccine to the residents of the State. As a preliminary matter, I will defer to my colleague, Commissioner Peter Boynton, on issues relating to planning and preparedness, information sharing and outreach, and collaboration, although both of us will try to answer your questions on those issues. I am sure you will have some.

As you mentioned in your introductory remarks, almost 2,000 Connecticut residents have tested positive for H1N1 infection, I want to point out that is really just the tip of an iceberg, and that for every person who has tested, there are many more people who became ill, stayed home and got better; they had seen a physician and not been tested. So when we see those numbers, people should not think that there are only 2,000 people that became ill; there were many more than that that became ill during that period.

Most of those folks who tested positive actually tested positive back in May, early on, because their focus was to determine where is this virus and is it here. And clearly, we saw the spread of this virus largely from the New York City area into Fairfield County, parts of New Haven County, and Litchfield County as well.

What I have found to be one of the most important indicators of widespread community transmission is looking at hospitalizations related to H1N1, and I think this has become an important marker for widespread community transmission of interest. Even though we were looking for this throughout May, we did not have our first hospitalization in Connecticut until the last week of May when we had four admissions for H1N1. So even though there was a lot of publicity about this in May, we did not see the impact on hospitalizations until then. In June, there were 104 hospitalizations related to H1N1, and there were 29 hospitalizations in July.

Pandemics occur in waves, and we should view that period as the first wave of a pandemic of 2009; very distinct, last week of May to the first 3 weeks of July. Actually, the peak week was the last week of June when there were 40 hospitalizations, a very distinct period.

What is remarkable is that we have only had two hospitalizations for H1N1 since the third week of July.

Which really suggested we had this first peak, and then we had a bit of a break and we are waiting for the second wave to start.

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<sup>1</sup>The prepared statement of Dr. Cartter with an attachment appears in the Appendix on page 204.

Chairman LIEBERMAN. Is that because it was not flu season.

Dr. CARTTER. Well, in many ways, we had a second flu season.

Chairman LIEBERMAN. Yes.

Dr. CARTTER. Pandemics do not happen in the normal seasonality of influenza, and this was our first wave. I think largely a number of schools in Connecticut run late compared to the rest of the country, and in the Northeastern part of the State, the schools were still in session until the end of June. And I think it is quite remarkable that within 3 weeks we saw a dramatic decline in the number of cases.

In general, though, the pandemic waves, whether it is in 1918 or 1957 or 1968, tend to last 6 to 8 weeks, which is also true for seasonal flu. Once seasonal flu hits, we usually see intense community activity for 6 to 8 weeks in a particular place, and then it moves on.

Chairman LIEBERMAN. Is there any guidance, based on history, as to how many waves a pandemic flu will go through? In other words, how many times will we be dealing with this?

Dr. CARTTER. Well, in 1918, there were three waves. Some people actually talked about a herald wave in the spring of 1918, but certainly in the fall, and then it returned in 1919. But I think what is important is that this virus eventually will become one of our seasonal flu viruses. When a new virus gets introduced that first year, first 2 years, it keeps returning. But eventually, it becomes one of the seasonal viruses.

So this one is here with us from here on out. It will change a little bit every year, just like all the influenza viruses, but in terms of what we are experiencing right now, this is characteristic of a new one.

Chairman LIEBERMAN. Interesting. Does that mean that the vaccine that has been developed for H1N1 may become part of the regular flu shot, as we all call it, that we take every year?

Dr. CARTTER. Well, that certainly would be the goal. The idea is—the way seasonal flu vaccine decisions are made in the United States is that there is a group that meets in February, chaired by the CDC and others, that looks at the experience of the influenza season, and then decides what should go in the seasonal flu vaccine. That information is transmitted to the vaccine companies. They start manufacturing in the spring and they start shipping in the summer. So this February, they will have to make a decision about what goes into the next year's seasonal flu vaccine.

The virus did not disappear over the summer. There were cases in summer camps. But importantly, we have not yet seen in Connecticut any evidence of widespread community transmission.

One of the systems that we use to track influenza-like illness is called the Hospital Emergency Department Syndromic Surveillance System, and that is a very long name. Essentially, more than 20 of our hospitals report electronically to us about syndromes that are seen in the emergency department, like the total number of visits. And what we are looking at specifically is the percentage of visits for fever or flu or that is written down in the chart. This has been an important indicator for us as to what is going on out there in the community, looking at emergency department visits.

While we have not seen anywhere near the level of activity in emergency departments that we saw in May and June, the percentage of visits for fever, flu are starting to go up, which may indicate that we are starting to see the beginning of the second wave.

Chairman LIEBERMAN. But so far, a very small number. How many did you say; two or three, actual hospitalizations?

Dr. CARTER. We have only had two hospitalizations since the end of July.

Chairman LIEBERMAN. Yes. That is great. We will see, though.

Dr. CARTER. I expect first to see the emergency department visits for fever, flu go up, followed by hospitalizations for H1N1. That would be our best marker of widespread community transmission of H1N1.

Again, influenza pandemics differ in their severity. This pandemic is at least as severe as seasonal influenza. Over the summer, CDC and State and local health departments looked at our experience from the spring and revised many of those guidelines and recommendations that were put out.

Our State public health laboratory has geared up for testing, but again, as has been mentioned, the focus of our testing is for public health purposes, and we are ready to use that to track this pandemic when it returns. We are going to focus on hospitalizations for H1N1. Our communication and public education plans are in place.

Now, as has been mentioned before, the best way to prevent influenza is with a vaccine. There have been a lot of work over the summer preparing it. I just want to give you some details about how we are going to be handling the vaccine here in Connecticut.

Chairman LIEBERMAN. This will be of interest.

Dr. CARTER. We began a preregistration process for public sector and private sector providers who are interested in administering H1N1. The model of the country is moving toward a private sector-public sector blend, where we have some vaccines given out by doctors in their offices as well as Public Health Departments at clinics.

Essentially, preregistering in Connecticut, the provider has to fill out a provider agreement, and the provider then has a list of terms and conditions defined largely by the Federal authorities that providers must sign off on in order to receive the H1N1 vaccine from the State. In this scenario, all of the vaccine is owned by the Federal Government and it is being distributed through State Health Departments out to providers.

There is no cost to preregister, and folks who register with our immunization programs are actually using a system that we have in place for the Vaccine for Children Program. Essentially, there is an existing program for getting healthy vaccines out there. So this endeavor is built on top of that system, and we are expanding it to other providers who want to give influenza vaccines.

As of this past Friday, we have had 1,439 providers who have signed on, indicating that they are interested and willing to give H1N1 vaccine. Examples of providers who signed up, we have OB/GYN offices, pediatricians, family physicians, internists, hospitals, community health centers, local health departments, and school-based clinics. In addition, there are 41 mass dispensing areas that are led by local health departments. We have broken the State into

regions and we are working with these mass vaccination areas to coordinate the public sector vaccine.

I wanted to talk about the amount of vaccine that we expect to see. As you pointed out, Connecticut is expecting to get about 500,000 doses of the vaccine sometime in October. This past Friday, the CDC had a media briefing and announced that there would be 3.4 million doses of the live, attenuated vaccine. This is the nasal spray vaccine, which will be available the first week of October. This is the vaccine that is coming first.

The nasal spray version, it is a nasal spray, not a shot, and it is approved for use only in healthy persons, age 2 to 49, who are not pregnant. So many of the people in those groups that you had talked about earlier, the target groups, actually cannot get this vaccine. So children who have underlying medical conditions, for example, or pregnant women cannot get the FluMist vaccine.

So this will be a challenge as we move forward. Many of those shots we are planning on prioritizing for healthcare workers. But based on our population, we should be getting about 38,000 doses of the nasal spray vaccine at the beginning of October. So at the health department, we will be meeting to talk about how best to distribute those doses.

Chairman LIEBERMAN. Am I right that you will be imposing or requesting that the private providers follow your judgment about vulnerable populations; in other words, who comes first?

Dr. CARTTER. Yes. Well, what is in the provider agreement is actually based on the provider agreement that was drafted and agreed upon by CDC and HHS, which includes those risk groups. So that is part of the provider agreement that they will sign.

Chairman LIEBERMAN. So is there any time frame now for the non-nasal spray vaccine that presumably will be effective or can be used by pregnant women and others?

Dr. CARTTER. From what I have heard in CDC briefings, the first supply of the shots should be 1 or 2 weeks after the nasal spray vaccine comes out.

Chairman LIEBERMAN. OK.

Dr. CARTTER. One of the things to remember about October is that much of our efforts to vaccinate people will be driven by the formulation of the vaccine that we received. There will be a lot of the nasal spray vaccine available because the yield of that vaccine was much better than the yield for those who are making the vaccine that is injectable. So we really will have to be very flexible over the course of October. We will have to see what we are getting and then get it to the people for whom it is indicated as quickly as we can.

Chairman LIEBERMAN. Thanks. Is that your testimony at this point?

Dr. CARTTER. That is my testimony. I would like to thank you for the opportunity to talk about this today and I would be happy to answer any questions you have.

Chairman LIEBERMAN. Thanks, Dr. Cartter. That was very informational, very helpful, and we will try to spread that word.

Commissioner Boynton, it is a pleasure to greet you for the first time as Commissioner. I have seen you in other capacities before.

Welcome as the Commissioner of the Department of Emergency Management and Homeland Security.

**TESTIMONY OF HON. PETER J. BOYNTON,<sup>1</sup> COMMISSIONER,  
CONNECTICUT DEPARTMENT OF EMERGENCY MANAGE-  
MENT AND HOMELAND SECURITY**

Mr. BOYNTON. Thank you very much, Senator. It is good to see you again. Thanks for your invitation to be here. As the others have noted, thanks for your interest and attention and the interest of your Committee and your staff. We really do appreciate that here.

In my role as Commissioner of the Department of Emergency Management and Homeland Security for the State of Connecticut, I would like to focus and emphasize on three themes today. The first is planning and preparedness; the second theme is information sharing and outreach; and the third is collaboration.

With respect to collaboration, you heard Dr. Cartter in his statement say that he defers to me for incident management. I have the exact same statement here saying I defer to him for medical issues. But as I was sitting here, I had to reflect that, really, we have a typo in our statement because we really are not deferring; we are collaborating.

We spend an awful lot of our time these days at the Connecticut Department of Public Health, and that terrific staff, likewise, spends a lot of their time with us at the Department of Emergency Management and Homeland Security. We have a tradition of working closely between those two departments, and all the more so now in preparing for the H1N1 outbreak.

That leads to my first theme, the importance of planning and preparedness. And as I have said, both agencies are working towards that, and let me offer some examples.

The State of Connecticut has a pandemic influenza response plan and an H1N1 vaccine distribution response plan. Both of these are authored by the Department of Public Health, which is the State agency designated by Governor Rell to lead the H1N1 response in Connecticut.

In addition to the statewide planning that has been done, we have also taken many steps to ensure continuity of operations in critical State government functions. Going all the way back to December 2005, Governor Rell directed State agencies to engage in pandemic continuity of operations (COOP) planning. Led by the Department of Administrative Services here in Connecticut, State agencies have participated in COOP training, and that culminated in the development of continuity of operation plans for 55 State agencies.

Each State agency in these plans has identified its essential functions, created a pandemic incident management team; and with that foundation in place, going all the way back to 2005, this past August, Governor Rell directed State agencies to review their continuity plans, convene their incident management teams in preparation for an H1N1-related incident.

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<sup>1</sup>The prepared statement of Mr. Boynton appears in the Appendix on page 228.

In its emergency management role, the task for my agency, Emergency Management and Homeland Security—we, like many people in government, refer to ourselves with our acronym, which is DEMHS. Our role is not only to maintain our own essential functions but also to assist others at the State and local levels to maintain their operations.

The role of DEMHS is to coordinate, as we do in every emergency, but in a pandemic incident, the coordination or incident management role is a bit different. Rather than dealing with a quickly occurring, acute type incident, such as a hurricane or tornado, we must be ready to deal with the long-term or chronic incident in this case.

DEMHS has established three activation levels. The first is monitoring, the second is partial activation, and the third is full activation. We are currently in the monitoring mode prior to any activation of our State Emergency Operation Center (EOC).

A key component of the monitoring mode is the subject of my second theme, information review and sharing and outreach to all our partners, as well as to the community at large. DEMHS, the Department of Public Health and the State Department of Administrative Services are working with the governor's office to provide accurate, current, and consistent information on the H1N1 situation.

Some examples. The governor has held three H1N1 summits here in the State: The first for school administrators K through 12; the second for higher education and residential schools; and the third just a couple of weeks ago for municipal officials.

These summits provided up-to-date information on H1N1 and State planning efforts from subject matter experts. They were all very well attended with hundreds of people present. They received media coverage, and as an additional way to reach out to the general public, these summits were broadcast on the Connecticut Television Network, which as you know is broadcast throughout the State.

The governor has also prepared public service announcements (PSAs), which have already begun to air on television and radio, and the first PSA emphasized the importance of personal preparedness. The governor's message also directs Connecticut residents to go to the Connecticut Flu Watch Web site, [www.ct.gov/ctfluwatch](http://www.ct.gov/ctfluwatch), for more information. And this Web site is a central Web portal not only for the public, but also for schools, universities, healthcare providers and businesses.

Beginning with the first outbreak of H1N1 in the spring of this year, information sharing with our partners, such as public and private health directors and providers; emergency management directors and municipal chief executive officers; school officials and State agencies, was accomplished through a series of regular telephone conferences that included both DEMHS and the Department of Public Health. We are going to use those teleconferences again this fall to reach out to the 169 communities and that key triad of officials, the chief elected official, the health director and the emergency management director.

In addition to that, DEMHS is also sharing information on the H1N1 incident through a computer system known as Web EOC.

Web EOC is a real-time, Web-based, situational awareness tool that allows us to communicate with Federal, State, and local partners. DEMHS uses Web EOC as a tool to communicate in particular with the emergency management directors and other officials at the local level.

Over 650 individuals across the State have been trained in Web EOC from 150 towns as well as State agency representatives. This tool not only allows us the pass information but rely on this to maintain the common operational picture across all partners.

My third theme, collaboration, leverages the success of all other efforts. I have already described many of the collaborative efforts that have taken place, and continue to take place, such as teleconferences, Web EOC, flu summits, and public education.

At the local level, collaboration is encouraged in a variety of ways. For example, each municipality, each 169, is required by State statute to have an all-hazards local emergency operations plan, which must be reviewed annually, not only by the local emergency management director but also the local chief executive and myself as well. And this all-hazards plan is important because it defines key roles and responsibilities for any emergency.

The State of Connecticut also passed legislation in 2007 creating an Intrastate Mutual Aid System that allows municipalities to assist each other. In addition, the State of Connecticut collaborates with other States—and we have some great examples of that—and our Federal partners.

For example, just this past July, Governor Rell joined five other governors and representatives from DEMHS and public health, participating in a national flu summit to discuss the spring time H1N1 outbreak and planning for the fall.

Finally, on August 20, the Northeast States Emergency Consortium held its quarterly meeting of State emergency management directors, chaired by the Connecticut Director of Emergency Management, Bill Hackett, in Brattleboro, Vermont. The August meeting was dedicated to H1N1 issues and included not only emergency management directors from each of the New England States and the State of New York, but also State public health directors; the FEMA Region 1 acting administrator, Paul Ford; Admiral George Naccara, who is the DHS regional coordination team leader; Admiral Michael Milner, with us here today; as well as Admiral Scott Deitchman from CDC.

So in closing, these opportunities at the local, State, regional and national levels for all to meet and exchange ideas, best practices, concerns in anticipation of a potential incident enhances our collaborative effort, and enhances it across geographic areas, across disciplines, and across levels of government, which will be essential.

Thank you very much, and I look forward to addressing any questions.

Chairman LIEBERMAN. Thanks, Commissioner. That was very interesting, very encouraging. I want to ask you one question at this point.

I presume that the kind of network that you have set up of communication and the idea that this is an all-hazards network really responds to the goals that I was talking about in my opening state-

ment. In other words, in the event of a hurricane, or a biological terrorist attack, as well as in the event of a flu outbreak, is the basic structure there to spring into action and is it multidisciplinary and multi-agency?

Mr. BOYNTON. I could not agree more, Senator. And as a great example, since 2007, there have been nine exercises that are related to H1N1, and yet many of them are not specific to H1N1. Some of them relate to continuity of operations planning and practicing that. Some of them refer to different aspects of the response.

But if you look at this history of exercises, some at the State level, some at the regional level within Connecticut, some with local partners, some with Federal partners, even though the topic may not have been an H1N1 exercise, you can see how they relate to this incident. It is very much along the theme of an all-hazards approach, which is an efficient approach to being prepared.

Chairman LIEBERMAN. Well, thank you for that. And people in the State should feel better about the fact that is coming together here.

Our final witness on this panel is Dr. Stephen Jones, Director of Outpatient Medicine and Center for Healthy Aging. As I get older, I am more interested in that subject myself; Chief Patient Safety Officer as well, at Yale New Haven Hospital.

Thanks, Dr. Jones, for being here.

**TESTIMONY OF STEPHEN G. JONES, M.D.,<sup>1</sup> DIRECTOR, OUTPATIENT MEDICINE AND CENTER FOR HEALTHY AGING, CHIEF PATIENT SAFETY OFFICER, YALE NEW HAVEN HEALTH SYSTEM**

Dr. JONES. Thank you, Senator Lieberman, and thank you for everyone here. And my apologies to you behind me who are getting my back. I am told that is my best side, so enjoy it.

It has been said that the most predictable thing about pandemic flu is its unpredictability, and that certainly holds true. The emergence of this H1N1 flu earlier this spring was an unwelcomed event, but I think in many ways it was also an opportunity for us to really look at our preparedness models and our readiness models, which we have been working on for a number of years. And I think this is a good opportunity for us to test those models.

It is important to understand that pandemic flu is a rare event. In the past 300 years, there has been only 10 pandemics that have occurred. The last one was 40 years ago in 1968, and the worst one occurred, as we all know, in 1918, where over 50 million people died worldwide, 675,000 Americans. And we would remind you, at that period of time, the population of both the United States and the world was significantly smaller than it is today. So this was an event of massive magnitude.

One of the problems with pandemic flu is that people do not appreciate the potential for how bad it can be because not many of us are still around from that period of time. Having said that, we should not expect the worse, but it is always out there.

Chairman LIEBERMAN. That is a very important point. Well, obviously, there have been deaths, as I said—the numbers that are

<sup>1</sup>The prepared statement of Dr. Jones appears in the Appendix on page 233.

growing are mild, but that is not a definite predictor of what is going to happen.

Dr. JONES. The two things we look at, Senator, are infectivity and virulence. This is a highly infective flu, as all pandemics would be, and virulence is the key thing. This is not a virulent flu at this point; 1918 was, and that really was the difference in the magnitude.

I would also remind everyone here that in 1918, the flu also began in the spring like this one did and was a mild form, and mutated probably in Europe during World War I with the troops and returned here as a mutated killer strain. So although we are hoping that is not going to happen, that is always a potential.

The present H1N1 flu is a direct descendent of the Spanish flu, and it is a milder version of it, obviously. So the one thing I would point out is that any deficiencies that we see in the strategies we have in place now would be magnified with a more virulent strain.

The challenges facing the healthcare system in a pandemic outbreak are truly daunting. Under normal circumstances, absent a pandemic, the following facts hold true for hospitals. On any given day, hospitals are operating at near capacity. Intensive care units that will receive our sickest of sick are almost always full. There are approximately 110,000 respirators, ventilators in the United States. Again, on an average date, 75,000 are in use. During normal seasonal flu, that goes up to 100,000. We have very little reserve in that capacity.

Emergency rooms these days are being used more and more by people coming in for their care because of lack of insurance or for whatever the reasons, and they are already literally clogged with people waiting for care. People sometimes wait for hours to days to get a bed in the hospital. Staffing is strained, particularly in nursing, and the recent economic downturn has only magnified that problem as well because hospitals have had to reduce staffing just to survive.

Hospitals operate in a just-in-time environment. In other words, we keep enough supplies to keep us operational for a day to 2 or 3 days. Blood products, perishables cannot be kept for long term. Even food and water has limited supplies. So in short, hospitals have limited capacity to flex up for any situation that may increase above their normal baseline.

As far as this pandemic situation is concerned, the biggest challenge facing hospitals with this current strain is their capacity to absorb this overwhelming potential for patients seeking care. It is estimated that at its peak, this pandemic could afflict 30 to 50 percent of the general population. Bear in mind, that healthcare personnel are also part of the general population. So you would have this perfect storm of patients requiring more and more care and healthcare workers not being there to provide it. Again, this in the setting where hospitals are normally operating at capacity to begin with and little margin to absorb any extra numbers.

Let me share with you just a few of the things we experienced early this spring in the Yale healthcare system with the emergence of the H1N1 pandemic flu. Private physicians were also impacted in their offices, and where do you think they sent their patients when they had too many? To the hospital. They sent their patients

to the hospital for medical care and they sent them there for testing, increasing our load of business as well.

Our emergency rooms saw significant increases in the worried well, people coming in just for sniffles, not really having the flu, who were concerned that they had pandemic flu. And to your point, Senator, not distinguishing between the symptoms of a cold versus the flu.

There were logistical challenges in terms of isolating people who are suspected with swine flu versus those who are not infected, and where we could put them at these particular numbers. Respiratory therapists, lab workers who tested these patients, were working overtime just meeting the demand of this particular population, and these were not significant numbers. In addition, CDC and the State were not always in sync on their recommendations to hospitals in terms of testing guidelines and recommendations.

Our infectious disease teams were worked to the hilt between patient care, patient hospital planning, media and just dealing with the particular pandemic situation. And amazingly, we saw flu continue into the summer. This is almost unheard of. Even though the cases were reduced, we do not see flu in the summer. Seasonality is one of those things that has to be addressed with pandemic flu.

Again, bear in mind this was all happening when the flu was not widespread, when our hospitals were fully staffed and operating at full capacity. The scenario would clearly be different, and likely will be different, when and if this flu reaches its peak in our communities.

Just other considerations quickly—schools were closed, sometimes appropriately, to address this, and maybe that is the proper approach in some cases. But when schools close, parents are required to take those children, and they drop out of the workforce as well. They are also healthcare workers like nurses. Supply chains may also be compromised with the pandemic; truckers, shippers, people stocking shelves, are less likely to come into work.

It is also not a local event. This is not like a hurricane or an earthquake. With a local event, there are services that can rush in from external areas to help. A pandemic, people are basically on their own, and hospitals and communities will not be able to tap into each other, to any great extent, to care for each other. And again, we are operating in a just-in-time environment, so those supplies are very limited. Availability and distribution of vaccines is also a challenge. We face the same things that were mentioned earlier, when will they come in, who gets them first, and how are they distributed.

Finally, Federal funding has been wonderful. Since several years ago when we first identified the importance of addressing this, Federal funding has appropriately stepped up. However, hospitals only receive a small percentage of this funding. In Connecticut, hospitals receive about 20 percent of this funding; in other States, hospitals receive even less.

So in summary, much has been done to prepare for this and it is commendable on all levels, Federal, State and community. The Yale Center for Emergency Preparedness works tirelessly to provide services to our hospitals and our communities to make sure we are ready.

With that in mind, we offer the following recommendations for considerations.

To help hospitals build into this system to capacity to respond and absorb patients under these surge conditions. Here in this particular outbreak, since it is mild, we are going to be seeing that impact mostly on the outpatient areas. If it gets worse, it will certainly be on inpatient as well.

To increase allocation of funding to hospitals to meet the cost of managing a pandemic, including staffing, overtime, training, pharmaceutical supplies and testing.

To improve the coordination between the State and the CDC in having their recommendations be timely and in sync.

To encourage—and I am going to step out of my Yale role for a second to speak as a personal physician—healthcare workers to step up and do the right thing and get their vaccines to protect their patients and also maintain themselves in the workforce.

One of the things I hear people say to me is, “Dr. Jones, I do not get the flu shot because I’ve never gotten the flu and I do not need it.” Well, that is simplistic logic. It is the same logic that suggests that if I have never gotten into an automobile accident, I do not need to wear my seat belt. It does not make sense.

Finally, we need to support and educate our general population on prevention, handwashing gels, and vaccinations. There was a study that came out recently that showed that putting hand gel dispensers into our elementary schools reduced spread by 20 percent and reduced teacher absenteeism by 10 percent. My own kids’ school had that done recently, and I think it has made a difference.

Recognition of the symptoms, educating the population and what we talked about earlier. And finally, preparedness; home planning, supplies, medications, advanced planning for child care, what have you.

As stated earlier, the most predictable thing about this is its unpredictability. We would strongly advise that at the conclusion, on the other side of this event, that we implement a statewide review and debriefing on what happened to look back as to how we can look at our victories and look at how we can improve things for the future. And having done that, we think we will come out of this, again, with the opportunity to improve our already improved situation and preparedness.

Chairman LIEBERMAN. Thanks very much, Doctor. That was an excellent panel, and thank you for concluding it.

Well, why don’t you just take a moment to develop that last thought that you had, that there ought to be a statewide review. You mean, after the flu season, for instance?

Dr. JONES. At the conclusion of this, more on the other side of this event, in the pass through, that we again get together with the appropriate agencies to look at where we had successes and where we had deficiencies.

I just want to underscore one other important thing about the seasonality. It is a misrepresentation, even in physicians, if they think that this is a winter event. Pandemic flu is non-seasonal. We have a southern hemisphere and a northern hemisphere. This is circulating the planet continuously, and we need to maintain our

readiness throughout the calendar year, not just in the winter and the early spring.

Chairman LIEBERMAN. That is a very important point. And, obviously, even as compared to 1918, and certainly as compared to 1919, a lot more people are traveling around. It is true that it coincided with World War I, so people were moving from here to there and back, but in the normal course of a day, there are many more people traveling the southern hemisphere and everywhere else, and coming back to the United States. So it spreads.

Dr. JONES. In 1918, the flu came across on the ships back from Europe and traveled the train routes across the United States. It took weeks. Now someone can be on a plane in Hong Kong and be in New York City in a few hours, so it is a completely different scenario.

Chairman LIEBERMAN. Let me focus in a line of questions that comes off of what you said because it really is important now, but it is important in terms of the larger, longer-term capability of the public health system to respond to other kinds of disasters which require surge capacity.

It is one thing to have a large national inventory of antivirals, that fortunately we had and we have spread them around now, to treat people with the symptoms, even to produce a vaccine, but quite another to try to increase the physical structure and all the services that go with it of a hospital or public health.

I mean, the fact that we do not have enough is why we have reached a national conclusion, and I cannot argue with it, that we have to assume when people are showing flu symptoms that it is H1N1. We are not going to go through a test because the people coming into the emergency rooms would overwhelm the emergency rooms. And as you say, in the hospital, generally, in terms of beds and in the emergency rooms, most of them, in our State and around the country, are already at or near capacity.

So short term, how do we plan for—and I agree with you; what you said is right. The only thing predictable about a flu pandemic is that it is not predictable.

Let's say it takes a negative turn and we need more bed space. What do we do?

Dr. JONES. Well, in that capacity, we have come a long way. Most of the hospitals, including the Yale system have put together plans for such a scenario, where we can ramp up a number of beds, either through moving to off-site areas, cutting areas that are normally done for elected procedures, elective surgery.

We have some capacity to ramp up space for beds. What we lack is staffing and equipment. A classic example are respirators. With a pandemic flu, if it was a severe pandemic flu, a number of people would need to be put on ventilators. We do not have those ventilators. What do we do when those people show up and you have to decide the ethical question of a young person versus an elderly person; who gets to decide to put that person on the ventilator?

So it is more equipment, Senator. It is more staffing than it is space. The space, the hospitals can find ways to deal with that in a short term. It is really not having anybody to stand next to that person's bed and provide those services to them.

Chairman LIEBERMAN. That is very interesting. One, I appreciate that the hospitals have those kinds of plans.

Would you say, Dr. Cartter, that most of the hospitals in this State have those kinds of fallback plans, for space anyway, if there is a surge need for additional bed space?

Dr. CARTTER. This has been a major focus of pandemic planning. One of the things that you need to remember is that we were all planning for a pandemic bird flu, and many of these plans have been developed over the last 3 or 4 years. But the structural issues that Dr. Jones mentioned are significant. It is not easy to increase the surge capacity of our acute care medical system.

Chairman LIEBERMAN. So longer term, as a Nation, what should we be doing, particularly in terms of personnel and equipment? Obviously, in a resource constrained time, this is more money that may need to be spent. Really, say what is the ideal as a Nation we should be investing in now.

Dr. JONES. To give us more capacity to see patients.

What has been happening across the country is hospitals are struggling financially, that they are going out of business. We have had hospitals around us close, and those patients wind up coming into our healthcare system, and that overburdens our emergency room and taxes our staffing as well.

As we have this domino effect of healthcare systems collapsing, it puts a greater strain on the established healthcare systems. And again, it just is a problem going in opposite directions. And so when we reach a situation, whether it is a pandemic or even a local event, we have limited capacity to step in and really provide help to these people.

So funding would help tremendously. Really, Senator, staffing is a major issue. We need people at the bedsides.

Chairman LIEBERMAN. And that is tough because, obviously, you cannot just bring—well, I suppose is something hit a particular area—now, this is national, but if there was a particular problem here, we could have a system for bringing personnel in for a short-term to deal with it from elsewhere.

Dr. JONES. We do table-top exercises in the State of Connecticut and through the emergency preparedness, just to do that, where the healthcare systems will step in and help each other, but pandemics are different.

Chairman LIEBERMAN. Let me come back to the flu in this way, just for a final question to you on this, and, Dr. Cartter, if you want to get into it, or Admiral Milner.

I presume that one of the ways we can take the pressure off of hospitals in the public health system, if this does get worse, is to have the doctors and the public be advised about how they can take care of themselves, unless it gets serious enough that they have to become inpatients at a hospital.

Am I correct? In other words, what people can do self-diagnose and what a doctor can do to take care of the patient in the office as opposed to sending them to the emergency room.

Dr. JONES. We have already started telling our patients who are coming into the hospital for routine care what to do in the event that they get symptoms, that they should probably stay at home if they have kind of run-of-the-mill flu symptoms that Dr. Cartter

mentioned earlier. The symptoms from the head up where it really represents a cold is not something you come into the emergency room for.

The other thing is that absenteeism, although a huge problem in a situation like this, is also exacerbated by presenteeism, people showing up for work who are sick and decide they want to be heroic and do the right thing. That is not in the interest of our communities. We encourage people who are sick with the flu, with fever, to stay home, and that is a message we are constantly striving to get out.

Chairman LIEBERMAN. Well said.

Admiral Milner, let me go to you in terms of the scope of what may happen. We were all unsettled last month when the President's Council of Advisors on Science and Technology released a report. And it may be that some of the numbers, which were suggestions, were taken too seriously. But they did say that there was a plausible scenario in which they could see up to half of the American population infected by this H1N1 flu, with almost 2 million hospitalizations and as many as 90,000 deaths.

Acknowledging what we will now call Jones' law, which is that the only thing predictable about a flu pandemic is that it is unpredictable, based on our current understanding of how this outbreak is proceeding, does HHS expect the United States to experience as large an outbreak that the Council of Advisors is suggesting?

Admiral MILNER. I think that we are planning for the worse and hoping for the best, like all of us. I think a lot of the messaging that has come out of the Department recently has been centering around the issue that Dr. Jones raised, that I know our State partners have been working on, and that is how to care for yourself at home, how to care for your children, and so on, to try to decompress some of the issues related to hospitalizations. I know, for example, Connecticut is working hard, as our other States are, on alternative care facilities and how we would staff those up and so on.

I think that, again, the jury is still out on how this is going to morph and how the pathogenicity of the virus will change. Again, I think all of us are trying to give the right tone to our messages that we have shared responsibility personally and we have to work together to get through this.

Chairman LIEBERMAN. So what I hear you saying is that you are not prepared to say that the 90,000 death projection is accurate, but you are not prepared to predict a number either because it is unpredictable.

Admiral MILNER. Correct.

Chairman LIEBERMAN. OK. We touched on this a bit. Last week—I will give you an intro to this—we held a hearing, the Committee in Washington, for the nomination of the new deputy administrator for FEMA, Chief Richard Serino of Boston. Probably you know him.

Admiral MILNER. Yes, sir.

Chairman LIEBERMAN. Well, he was quite impressive, he heads Boston's emergency medical services, and he relayed what I find to be a striking statistic about Boston experiencing the flu last spring, which was that 23,000 residents were stricken with H1N1, and

that 11 percent of the student population had it—so this is obviously an important factor for the schools, the judgments to make.

I know that the government is trying to encourage schools, at this point, to stay open, even as they experience cases of H1N1 among their student population.

I wanted to ask you, what are we saying to the schools about what the threshold is for when a school should in fact close?

Dr. Cartter.

Dr. CARTTER. Let me also answer and comment on the earlier question that you raised about severity and about that report because it leads into the discussion of education.

Pandemics differ in severity. And also, as part of that, they also differ in the number of people that are affected. The 1918 pandemic affected about 30 percent of the population, the 1957 pandemic, about 20 or 25 percent, and the 1968 pandemic was 40 percent of the population was affected. So that report was really describing the range of possibilities because we do not know yet exactly what percentage. But so far, this appears to be most similar to the 1957 pandemic, and we are looking more at a range of 25 to 30 percent rate of illness in our population.

Seasonal influenza is about 10 to 15 percent of the population every year, although that can vary, but that gets to your perspective. And looking at our control methods, obviously schools are important places of transmission for influenza, but we also have to look at the severity of the disease. And this particular illness, at least at this point in time, does not seem to be more severe than seasonal flu.

If this were a 1918 situation, the recommendation of the Federal Government, as well as the State, is that schools would have been closed at the very beginning of the pandemic, and they would stay closed for 6 to 8 weeks. Given the severity of this and that this is actually very acute, similar to seasonal flu, we are not recommending that schools close to control this illness, as we do not make the same recommendation for seasonal flu. We would be closing schools every year in that case.

The point here is that the best place for well children to be is in school; the best place for sick children to be is at home.

Chairman LIEBERMAN. That is the key. The students who have it should go home.

Dr. CARTTER. Exactly. And working with parents, working with teachers and others to make sure that there is a continuity of education is critical. And one of the things that we have been doing with our education partners is working on that piece. As for a threshold, it really varies. It is important to point out that the State of Connecticut Department of Public Health, did not recommend any school closures in May or June. We work closely with our communities to keep schools open.

The second point along that line is that we need to be aware that there may be circumstances where schools need to close because there are not enough students and teachers present to have a reasonable or meaningful class. And we know of schools that reached 40 to 50 percent absentee rates last May and June, those who are getting into the area where they have to make an administrative decision does it make sense to hold class. And we let that decision

be made at the local level between the school superintendent and the local health director.

Chairman LIEBERMAN. I assume, incidentally, that if a student is sent home or a worker is sent home from a job because they got the symptoms of H1N1, they really should stay home. I mean, in the sense of not going out to the mall or going to a movie.

Dr. CARTTER. The term used by CDC is social distant things; you go home and then go to the mall, and that defeats the purpose of going home.

One of the problems that we have in our society in terms of this is that many children may be going home to a home where nobody is present because they are at work. So this is a difficult issue at the community level because not every child can go home to a mother or father or other significant person to take care of them. We have to do just like we did in 1918, to call on families and friends to take care of those who are sick and make sure that they are not at school.

Chairman LIEBERMAN. Of course, I never knew my grandmother because my dad was three when she got the flu in 1918 and died. But the picture they painted, not to frighten anybody from doing something altruistic, was that she was healthy and she started to help other families who were affected by it, and then she got it, and she died pretty rapidly.

I wanted to ask you a medical question just for the record.

So far, what has been the effectiveness of the antivirals? In other words, we see symptoms that look like it, and the person has not received the vaccine. We give them Tamiflu or the other one, I forget what it is.

Are they working, Dr. Jones?

Dr. JONES. The antivirals are one of those things that people have been clamoring for because they think they are a panacea, and they probably do not represent that.

First of all, if the antiviral is to be effective, it has to be given very early on in infectivity, within the first 48 hours. And the CDC presently is not recommending these medications be used prophylactically or just for kind of simple, run-of-the-mill symptoms. It really should be reserved for those who truly needed and are demonstrating either underlying immunocompromised states or situations where they are advancing and becoming more critically ill.

The Tamiflu at this point probably is responsive to treating the infectivity, but, again, it is not something that would be recommended at this point as a first line treatment.

Chairman LIEBERMAN. I take it that in a lot of cases of people with H1N1, they will get over it because their bodies ultimately reject it or it finishes its course and the body gets better again. Is that correct?

Dr. JONES. It is like a flu shot you get to keep from getting the virus. It is essentially the same thing. You develop immunity through a flu shot or through infectivity. Most people will get over this just fine and have some level of immunity as a consequence. We have to have this balance between people who overreact to these situations and are too complacent, and the answer lies somewhere in between.

Chairman LIEBERMAN. And at this point, some of the populations that you have designated as vulnerable on the list for vaccines, they are showing a little less natural resistance to it, some of them.

Am I right, young children particularly?

Dr. JONES. Young children have less immunity because they have not been exposed to this. People born before 1957 probably have some background immunity just from having been exposed to this in the past.

Chairman LIEBERMAN. This gets to the healthy aging idea again.

Dr. JONES. It gets to the healthy aging as well.

Chairman LIEBERMAN. Just a few more question, and then we will go to our second panel.

Commissioner Boynton, you mentioned that your office is responsible for reviewing all local emergency operation plans. Since you have learned of H1N1 at the end of April—I know you are new on the job, but from what you have found, how would you rate the seriousness with which different communities in Connecticut have prepared for H1N1 over the last 6 months?

Mr. BOYNTON. One example I think of the seriousness, Senator, is that the requirement for an annual review is a new one that started just this year by State statute. And under the statute, the reviews are not due until January. By the end of the summer, already over a third of them were in, which is way ahead of schedule. I do not think that is because those communities do not have anything else to do.

So I think they are taking it seriously. And I would also comment that at the flu summits that the governor hosted, particularly the third in a series of three, which was focused on municipal officials, there was a huge turnout, tremendous interest, and we had panels from a couple of municipalities. In fact, I think some of them are in the second panel with you today. And they spoke of the type of actions they took back in April, which I think showed seriousness and preparedness even back then, which I think, again, reflects on what Dr. Cartter said, that we are not just now starting because of H1N1. Really, this preparation goes back to 2005 or earlier with substantial preparations for the potential avian pandemic. And it does not mean our work is done, but I think there is a substantial record of preparation because of that.

Chairman LIEBERMAN. Admiral Milner, I must say that listening this morning, I am encouraged by the extent of the cooperation that I have heard testified to between the State and local government, and between the Federal, State and local. I want to ask you from your larger regional perspective—I do not want to put you in the awkward position of grading Connecticut in the presence of the people you are grading.

Are we looking good compared to the other States in the region that you oversee?

Admiral MILNER. Absolutely. No question that Connecticut is one of the leaders, and they have been one of the leaders through all of this planning that we have discussed here. We did an exercise in December 2007, where it was open to all of the States. Connecticut was a very active player. Dr. Cartter was one of our key participants.

So from my perspective, looking at all the States, as I mentioned earlier, I am glad that I live here and my family lives here in New England because all of the States have helped each other stand up even more. And we had a call first thing this morning at 7:30 with updates about what their thoughts are regarding some of the third level of funding that is coming out of CDC, and what some of the incidence is in their States and colleges and so on.

So they are helping each other, and by doing that it is raising the boat for all of us. And I would say that Connecticut is in the top of the top.

Chairman LIEBERMAN. Thank you. Yes, Commissioner Boynton.

Mr. BOYNTON. Senator, if I could just add to that. There is a Federal publication that talks about how States can approach volunteers to help, not just through the H1N1, but with all hazards. And it gets to your earlier point about the efficiency, the economy, and the effectiveness of an all-hazards approach.

In this publication—I forget what page it is, about a third of the way through—it states that Connecticut has the best practice for addressing liability issues for volunteers, and the State worked with the legislature, and a lot of that work is now behind us.

But it is another great example where that work in addressing liability issues for volunteers was not directed specifically for H1N1, but in the all-hazards environment, it helps prepare us for H1N1. And I do not want to say all is done because it is not. There is more work to be done, but it is another example where Connecticut is cited as a best practice.

Chairman LIEBERMAN. It is good to hear.

Let me ask the last question. I am going to leave you out of this, Admiral Milner, because I am going to ask the other three, briefly, if there is anything particular that the Federal Government is not doing right now to be of help to you in dealing with this H1N1 pandemic? I ask that since I am from the Federal Government and I am here to help.

Dr. CARTER. Well, I am here from State government and I am here to help. The way I would approach that question is to say that Mother Nature has not read our pandemic plan. And at this point in time, we are close to starting the second wave of a pandemic of 2009.

We need to be flexible, not only at the State level but also at the level of the Federal Government because as much as we plan, obviously things can be different. We have the virus that is unpredictable, and we also have a supply chain that is going to be challenged, as well as the influenza vaccine arriving in different forms and various times. So this is really the moment of truth at this point in time moving forward.

Chairman LIEBERMAN. Good point. Commissioner Boynton, anything more?

Mr. BOYNTON. Sir, I would just say it depends. As we go forward, it depends on the severity of the incident. I think we are pretty well schooled across the country with how we get resources to respond to more traditional incidents: Hurricanes, tornados, ice storms, etc.

I think it is important to remember that if incidents are severe, we do have a system of incident management that relies on sup-

port. As Dr. Jones pointed out, the Mutual Aid Support is more likely to not be available for a pandemic, because if we use the equivalent of an ice storm, we could all get this ice storm no matter where you live.

Chairman LIEBERMAN. Right.

Mr. BOYNTON. So we might not be able to borrow from our neighbors. If it is severe enough, our method of incident management relies on support, for example, like the Stafford Act. We are pretty clear on how the Stafford Act works in ice storms, hurricanes, and tornados. We need to be clear on how that would work if the severity of this incident is significant.

Chairman LIEBERMAN. Good point. Dr. Jones.

Dr. JONES. The final thing I would say is this. We all know that vaccines seem to be one of the central approaches to addressing this issue, and we have come a long way towards vaccine development, and the government has done wonderful things in terms of funding and reducing liability to pharmaceutical companies in the development of these vaccines. However, vaccines right now take a significant amount of time to make because it is mostly egg-based technology. We have the capacity now to improve that. That is in process right now. Those efforts need to be supported.

The final thing, I mentioned early on, this is an opportunity as well as a challenge, and the opportunity is to learn. And again, we really need to step back at the end of this and look at what those lessons are.

The final point I will make is this. People have a misconception that since pandemics are rare events and they occur every 30 or 40 years, and that we may be off the hook come next year. It does not work that way. The probability of a pandemic next year, and the year after, and the year after is no less than it was prior to this particular event as well. And that is why we need to be on our toes preparing and ready to go.

Down the road, we will have the technology and the science to address this with, hopefully, a universal vaccine where we can stop having to create vaccines that address one particular influenza. That is a significant way down the road, but we have the opportunity to make that happen and we need to get on the ball to do that.

Chairman LIEBERMAN. Thanks. Those are very constructive suggestions. And to take your words, Dr. Carter, I think, at the Federal level—I speak for Congress, but I talk to Secretary Napolitano at the Department of Homeland Security enough to know that I can speak for her on this—we are staying flexible. It is a good point. So far, we are feeling fortunate that the intensity of the flu has not been as great as we thought it might be, and yet we know it is unpredictable.

There is a history that no matter what the times economically, that Federal Government responds to disasters. If this becomes more severe, I am sure we will do everything we can, both with financial assistance and perhaps with some provision of more personnel from Federal Government, including the military.

We have now divided FEMA after Hurricane Katrina, in addition to their national headquarters, they have 10 regional offices, which drill for a series of disasters that could potentially happen in those

regions. And each one of those regions has representation from various Federal departments, including the military. There is one in each one of those.

You have been really helpful. I thank you for what you are doing everyday. I thank you for the testimony that you provided here. I think it is a great idea when this is behind us to do a lessons learned, and then we will do our best to learn from what you learn to protect us into the future.

Have a good day. Thank you very much.

We will now call the second panel

Julie Polansky is a parent from the Vernon Public Schools; Roseann Wright is Director of Public Health for the City of Waterbury; Daniel Aloï, Manager of Business Continuity Services at Aetna, Inc.; and Michael Kurland, Director of Student Health Services at the University of Connecticut (UConn).

I want to thank the other folks who have come out, a lot of whom who have responsibilities in the public and private sector related to dealing with outbreak of H1N1.

Well, good morning. Thanks for your patience. I hope you have found the first panel as interesting as I did, although you have probably been hearing a lot of that give and take all along the way.

We thought that it would be good to have—I was about to say just a normal person here; not to say the first panel was abnormal, but a parent to reflect on their experience with this. Julie Polansky has come to do exactly that. So we welcome your testimony now.

**TESTIMONY OF JULIE A. POLANSKY,<sup>1</sup> PARENT, VERNON  
PUBLIC SCHOOLS**

Ms. POLANSKY. Thank you. As you mentioned, I am a working parent within the Vernon Public Schools. I have two children in the school system right now. I have a middle schooler and an elementary school student. And we did have an experience in the spring of this past year, where our schools closed due to suspected cases of H1N1.

It was shortly after spring vacation and Vernon Public Schools closed for 2 days due to a suspected case. Most parents, including myself, learned of the closure via local television news outlets. The school system initially did not notify parents via e-mail or phone calls. However, a notice was posted on the school's Web site.

Since it was an unexpected closure, or not a snow day, I did hear of a few parents who had not watched the local news and were unaware of the situation. Having and utilizing an emergency notification system within the school system would have greatly helped facilitate communications to parents.

Additionally, communication regarding the reasoning for the closure was vague. Parents were aware the closure was due to H1N1, but initially did not receive information about the number of suspected cases, the location, or the school of the potentially infected individual or individuals. This lack of communication caused unnecessary speculation and rumor on the part of parents and the community.

<sup>1</sup>The prepared statement of Ms. Polansky appears in the Appendix on page 236.

Additionally, guidelines for the community of Vernon were lacking. Due to the closure of schools, all Little League practices and games were canceled for the 2-day period. In fact, on the day that administration closed the schools for the following 2 days, which was announced on the news outlets at approximately 4:30 p.m., parents and players were turned away when they arrived for practices at the various Little League fields.

In the case of Vernon, the suspected case that caused the closure turned out to be influenza but not H1N1. I understand administration's cautious decision in the interest of the children, however, it was merely one suspected case, and it may have been adequate to either wait for the results of testing or close the one impacted school, not the whole district.

I would also like to point out that I do believe the closure of schools could be truly warranted if a significant number of children and/or staff become infected in one location.

The impact of the 2-day closure on myself and a number of other parents was relatively significant. For myself, I work locally, I have a flexible schedule, but I was forced to rearrange my work day and make arrangements with friends for daycare. Many other parents simply utilized daycare facilities for their elementary age children.

So my question at that point becomes, does the closure of schools actually help to stop the spread of the school virus? What is the difference between the children being together at school or at a daycare facility, assuming they are healthy?

I would like to also point out, I have no problem taking time off from work and keeping my children home if they are sick, however, if schools are closed and my children are healthy, I will continue to allow them to play with their friends.

Subsequent to the closure, the system distributed the State guidelines for ill children, and in my view, these guidelines are clear and reasonable. Guidance from school administration regarding the make up of the days that the district had to take off was also vague.

In Vernon, initially parents were informed that the days would need to be made up at the end of the school year. This would have made the last day of the 2008–2009 school year, June 30. The situation caused issues for a number of parents and staff, since it was the Fourth of July week.

Subsequently, the Board of Education reversed the decision, and through negotiation and coordination with the teachers' union, the students did not make up the H1N1 closure days. This situation caused confusion for a number of parents and staff because they went back and forth on whether the days would need to be made up. Some guidelines or guidance from the State on whether districts need to make up these days would have been helpful.

My hope for the current school year is for clear communication and careful preparation. I am happy to report that just last week, the Vernon public school nurses distributed a flyer to parents outlining the district's recommendations on how to stop the spread of flu and other illnesses. The flyer included details of flu symptoms, recommendations on how long children should remain home, information on the vaccine, and prevention kits. It was also noted that the nurses are working closely with a local physician and the De-

partment of Public Health to monitor the flu condition and make decisions about the best steps to take concerning schools. I hope the district will continue to provide periodic updates via additional flyers, guest speakers at Parent Teacher Organization meetings and the school Web site.

In terms of preparation, I believe it would be prudent for schools to have funding set aside for continuous supplies of hand sanitizer and periodic extra cleaning of the building. These preventive measures will help to avoid closures in the future. Since most school budgets are extremely lean, I wonder if it is possible to have State or Federal funding for these preventive measures. Also, a quick note. Just Friday, parents started receiving notices asking if they could donate hand sanitizer, tissues, all of these items to also help the situation.

Guidance from the government is also crucial. Keeping parents informed is part of all these guidelines. So guidelines regarding who should get a flu shot, whether sick children should visit their primary care physician, how long a child should remain home after being ill, when and if a school should close, and how community sports, groups, or leagues should handle any outbreaks should be readily available to the public.

Thank you for the opportunity to participate in this hearing.

Chairman LIEBERMAN. Thank you. That was very helpful. I hope and I would guess that some of the response of the Vernon public school system was to the complaints that you registered last spring. Do you think so?

Ms. POLANSKY. Oh, I absolutely do. I think that what happened was they were being extra cautious in the interest of the children. And it also was a result of all of the media, and just not knowing what to do at that point. But I also believe that they have set a number of guidelines this year to help the situation.

Chairman LIEBERMAN. Right. Your conclusion is that they are handling it a lot more sensibly this year than they did last spring.

Ms. POLANSKY. Right.

Chairman LIEBERMAN. That is good. And the advice now nationally and from the State is not to close schools, but to send kids home who seem to be sick. You are suggesting a problem or you are describing a problem, one part of it here, which is very hard to deal with. But you are absolutely right. If the child comes home from school, and for various reasons, because of the pressures and demands on the family, the child ends up at a childcare center, that is no better.

Ms. POLANSKY. Right.

Chairman LIEBERMAN. And that is something that is hard for the government to handle. It is something we have to ask parents to try to do their best to avoid spreading it.

I like your idea about the hand sanitizers. The experts tell us that just washing with soap and water is not bad, but it is obviously easier—I was out at Stop and Shop the other day. It is too bad my wife is not still here because she would say he hardly ever goes shopping, but he is going to talk about that today. [Laughter.]

But anyway, as I walked in, there was a container with hand sanitizers there. Around the Capitol, they are all over, and in Washington, that is important.

Thank you very much for being a good parent and a good citizen and coming forward and telling us what you did.

Second, Roseann Wright, Director of Public Health, Waterbury, Connecticut. Welcome.

Ms. WRIGHT. Good morning, Mr. Chairman.

Chairman LIEBERMAN. Good morning.

**TESTIMONY OF ROSEANN WRIGHT,<sup>1</sup> DIRECTOR, WATERBURY  
DEPARTMENT OF PUBLIC HEALTH**

Ms. WRIGHT. Thank you for this opportunity to testify. I am Roseann Wright, Director of Public Health for the City of Waterbury. I am here today to share our experiences in Waterbury about how the Public Health Department, the school district, and the school nurses dealt with the influenza outbreak.

The Public Health Department employs three nursing supervisors, 39 nurses, 20 health aides, and cares for over 22,000 students and 39 public, private and parochial schools. And with the 22,000 students, that is a fifth of Waterbury's population.

As the Director of Public Health, I cannot place enough stress on the importance of the school nurse in the academic environment in terms of identifying, assessing, and tracking communicable disease. Identification of a communicable disease outbreak by the school nurse is also a potential indicator of a communicable disease outbreak within our community. The school nurse is often the first staff member to identify common signs and symptoms of a communicable disease and alert public health administrators.

During the pandemic of H1N1, the Waterbury school nurses became integral in conducting surveillance in school populations. Early in 2009, a number of confirmed H1N1 cases were reported with increasing frequency, prompting the Public Health Department to proactively educate the public and minimize the spread of H1N1.

The Public Health Department planned for the possibility of this becoming our next pandemic, and we needed to protect our school personnel, such as our school nurses and our health aides, and to do this, we set up several public health initiatives.

With the school nurses, we reviewed the number of incidents of absenteeism to determine if outbreaks were occurring in our schools. The school nurses and the supervisors became our sentinels for the community's health. We also increased communications between the Public Health Department, the school nurses, the superintendent's office, and all of our private and parochial school principals to see if any H1N1 cases were confirmed in their academic environment.

The Public Health Department sent all of our environmental sanitarians to inspect all the school bathrooms to ensure hand soap, paper towels, and hot water were available. We also had bilingual communication sent to parents of the school-aged children, addressing signs and symptoms of H1N1, prevention tips, respiratory etiquette, and information regarding swine flu.

In January 2009, the Public Health Department conducted a table-top exercise with the school nurses regarding the roles and

<sup>1</sup>The prepared statement of Ms. Wright appears in the Appendix on page 238.

responsibilities if a pandemic were to occur. This was an opportunity for the nurses to immerse themselves in a scenario that would test the responses if and when the pandemic did emerge.

In addition, the school nurses also participated in a collaborative effort with the Waterbury Fire Department to distribute H1N1 flyers to 12,000 households. This was accomplished by staff literally walking door to door and speaking to residents face to face.

As the Nation experienced school closures, so did Waterbury, as the superintendent of Waterbury closed an elementary school for 2 days. In order to avoid additional school closures, the nurses worked collaboratively with the Board of Education, and the following non-pharmaceutical mitigation interventions began.

We instituted several infection control techniques, installation of hand sanitizer dispensers for all the health rooms and the cafeterias. We distributed disinfectant wipes to the school nurses and teachers. We encouraged frequent bathroom breaks so students could wash their hands, especially in the elementary schools. In addition, we encouraged all students and staff to stay home when they are ill, and we encouraged them only to attend school when they are well. The custodians are also cleaning all surfaces that are likely to have frequent hand contact.

In anticipation of the 2009 school year, the superintendent sent out a letter to all parents and guardians to highlight proper protocols when a child exhibits influenza-like illnesses and how the schools will maintain a healthy environment within the school district. The letter also mandated that students must stay home until signs and symptoms are gone and not to return for 48 hours rather than the current guidance of 24 hours.

This message was also shared with private and parochial principals, so our message was consistent throughout Waterbury.

In anticipation of the 2009 school year, the Public Health Department began to prepare for H1N1, which consisted of several staff meetings. Data collection tools were developed, which were used to monitor students with influenza-like illness. These new data collection tools will allow the school nurse to monitor siblings and will determine if a child has been returned to school per the superintendent's 48-hour guidance. In addition, school nurses will conduct a brief risk assessment of the entire student household to determine if other family members are ill.

The school nurse is also responsible to identify students and staff with special medical needs, which will potentially put them at higher risk for complications as a result of seasonal influenza. The school nurses are our medical professionals in our academic environments and can offer education to students and staff, as well as mitigating interventions that will help minimize the infectious agent of H1N1. Last year, our 39 school nurses encountered 175,000 students through our health rooms. The school nurses have the ability to provide continuous, repeated education to this population.

The Waterbury Public Health Department is also utilizing State and Federal guidance documents as a tool to develop specific strategies that are customized to the needs of Waterbury's academic environment. These guidance documents are assisting the health department and school nurses to minimize the spread of H1N1

amongst our students and school staff, while limiting the disruption of day-to-day activities, thus facilitating educational continuity.

We continue to prepare our school nurses by informing them of new guidance from the CDC and the Public Health Department in Connecticut. Waterbury recognizes we are not alone in the prevention of H1N1, and we share the same challenges and burdens as other municipalities across the State of Connecticut and the Nation.

The Public Health Department administrators are constantly meeting with other directors of health and nursing supervisors from various forums, such as Connecticut's Department of Emergency Management and Homeland Security, Region 5. And here, we share our important information, such as mitigation strategies, lessons learned and other valuable information, all of which is shared by our school nurses.

In conclusion, as the pandemic continues to increase in intensity, the school nurse will continue to provide care to our students, educate our students in keeping themselves healthy and act as our sentinels for the community's health.

Chairman LIEBERMAN. Thanks very much, Ms. Wright, for a very thorough report. I will have some questions for you after we hear the final two witnesses.

Daniel Aloï, as I mentioned, is the manager of Business Continuity Services at Aetna.

So we have heard from a parent, a public health official at the local level, and now we want to hear some thoughts about how businesses are dealing with this problem. Thanks for being here.

You have a great title, the Manager of Business Continuity Services. Tell us what that means.

Mr. ALOI. Yes. The terminology used in the first panel is continuity of operations. My job basically is to make sure we keep the lights on, the phones answered, the claims paid, the patients communicated with, and all our critical customer facing operations, as well as, of course, the core function of keeping the corporation running as well.

Chairman LIEBERMAN. Presumably, in an emergency situation.

Mr. ALOI. Yes.

Chairman LIEBERMAN. You are, in a way, sort of the secretary of emergency management for Aetna.

Mr. ALOI. You could say that. And we do subscribe to an all-hazards plan, as mentioned in the first panel, where we have a central team, crisis response team, that is well versed and practice over and over again in dealing with minor outages while preparing for the major outages due to hurricanes or widespread disaster. It is an interesting job; never a dull moment.

Chairman LIEBERMAN. Yes, I bet. What is your background?

Mr. ALOI. Emergency planning since 1983. I was a manager of emergency planning for Millstone Nuclear Power Station, where we prepared plans, procedures, training exercises, and worked with State and Federal local agencies in exercising those plans, basically from one frying pan to another.

Chairman LIEBERMAN. Yes. It sounds like you are ready.

So you are going to tell us what Aetna is doing in regard to this. Do you give advice to your business clients about what they should do?

Mr. ALOI. Yes, we do, actually.

Chairman LIEBERMAN. Well, go ahead. I am interrupting you.

Mr. ALOI. Since 2006, again, we took the first guidance that came out—actually, late 2005—very seriously. We established teams to deal with internal operations, but as well as communicating and creating plans for communicating with our plan sponsors to help them help their own members and creating their own operations deal effectively and weather a pandemic along with us.

Chairman LIEBERMAN. Very good.

**TESTIMONY OF DANIEL ALOI,<sup>1</sup> MANAGER, BUSINESS  
CONTINUITY SERVICES, AETNA, INC.**

Mr. ALOI. Aetna is pleased to be in attendance today to share our plans and experience with the panel. We are members of the Homeland Security Critical Infrastructure Subcommittee on Health Care and are actively involved with the public and private sector in advancing all preparedness, as I said earlier, since 2005. We are continually learning, as everyone is, and constantly testing our plan. We see no limits on the sharing of information when it comes to the public good and the Nation's resilience.

Aetna occupies over 100 facilities at various sites throughout the country which house a variety of Aetna departments and functions. We are fairly dispersed throughout the country in our operations center, which is a strength for us.

To prepare for pandemics, Aetna has developed many recovery and coping strategies to ensure continuity of operations and to keep employees healthy. Although not implemented solely for pandemic planning, among the most notable element is our very robust telework program, with large numbers of our employees already able to fully function from home effectively. Roughly one-third of our workforce today work from home.

The second most significant capability includes a comprehensive work reallocation process, where customer service calls and claim adjudications can be redirected to other Aetna offices with almost seamless transition. We are very fluid in the way we can transition work back and forth amongst our geographically dispersed work sites.

Another important element is that Aetna has a considerable bench of contingent workers who are trained and can augment critical staff if there are high absentee rates, as we would expect. Contingent workers are routinely used to help during peak periods. Typically, they can consist of trainers, quality service folks, management that may have had some training in that area. It is basically needed every season.

Actually, the first part of the year is our most intense period where all the plans renew. Our customer service people see an overload at that point. So we have the ability to bring in additional people that are trained and qualified and we test them every year.

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<sup>1</sup>The prepared statement of Mr. AloI appears in the Appendix on page 244.

Chairman LIEBERMAN. That is fascinating. These are people who are not working when you are not calling on them?

Mr. ALOI. These are people who are doing other functions within the corporation—

Chairman LIEBERMAN. I got you.

Mr. ALOI [continuing]. Functions that we can put aside and change our work model to prioritize on the most core functions.

Chairman LIEBERMAN. Do you use retirees at all in that way?

Mr. ALOI. We have a program to look at retirees and to call them back. We are working on that. That is one of the things we want to develop.

Another important line of events in our capability is to keep employees healthy in the face of a pandemic. Aetna has created many strategies to accomplish that. It starts with a short and pointed, online course that employees are expected to take. The course provides instructions on hand hygiene as well as sneeze and cough etiquette, because we believe, as others do, that this can be one of the best measures in minimizing the spread of virus in the workplace. This course is available on line for our employees. It also is available for our members and our plan sponsors as a public service.

Aetna has placed hand hygiene and stay at home when sick posters at all our Aetna sites as a constant reminder, along with permanent Internet and home page messaging on our Intranet Web net page. Aetna's human resources policies strongly encourage sick persons to stay home when symptoms appear with non-punitive, pandemic pay policies. Beyond these strategies, Aetna has provided a personal supply of antiseptic hand sanitizer to all office based persons within our facility, along with the common bulk space dispensers you mentioned earlier.

Aetna has purchased a stockpile of surgical masks and has deployed these to site crisis managers, along with instructions to issue them to any person that is symptomatic or who otherwise feel they may be coming down with the flu. Sick persons will be sent home or to a healthcare provider if symptoms are severe. There is also provision to quarantine that person in the office until they are sent home and taken care of.

Another important planning element is our rapid telework deployment capability for office based workers. This is accomplished with an infrastructure, procedures and plans where we can transition additional large numbers of workers to a temporary work-at-home setting within days, leveraging the Internet.

We implement a scaled-down version of this each winter when severe weather occurs. During a traditional nor'easter, we typically have only 10 to 20 percent of our employees coming into the Connecticut office, and our customers see little or no impact. Under rapid deployment to telework, employees will be prioritized by mission critical function, as well as by their technological readiness to transition, i.e., broadband capability.

Efforts will be made to adhere to CDC guidance, where employees in high risk groups are offered an opportunity to work at home consistent with employment laws. At many sites, there will still be a need for office based workers to come on site no matter the threat to keep serving our customers. For these employees, social distancing strategies will be employed. To that end, we have plans

ready to cancel or curtail physical meetings and substitute virtual meetings through our robust teleconferencing network capability. Additionally, we will enhance facility cleaning, control visitation, eliminate unnecessary travel, and spread out employees geographically if needed.

Efforts will be made to coordinate actions with local and State health officials to adhere to any triggers that may be provided by health officials for taking additional actions. All site crisis leaders have been instructed to establish two-way communications with their local and State contacts so they are apprised of the local situation as it changes and they are advised of local actions that should be taken.

The objective of all this is to flatten out the absentee curve at all affected sites and maximize our production to serve our customers and members during the peak of each wave. It is our hope that if strategies are employed effectively, we believe we can lessen that peak absentee curve by about 5 to 10 percent, and this would make a big difference if we could do that. There is no scientific evidence in that; that is just our belief internally.

Last, a separate but very significant part of our response capability is the ability to deal with member needs due to widespread disasters, such as hurricanes, wild fires, or terror attacks. We have established a dedicated team to review health benefit policies that may need to change due to a provider network overload, or due to provider network failure, or due to a mass evacuation as in Hurricane Katrina.

Changes once identified through our evaluation or due to regulator order will be communicated to members and plan sponsors so that they can avail themselves of alternate ways to obtain the care they need. This process has been successfully demonstrated on September 11, 2001, and in natural disaster after disaster, in recent years, and would be implemented if necessary during a pandemic as well.

We thank you for the time today.

Chairman LIEBERMAN. Thanks, very much, Mr. Aloï. That was really interesting. I am going to come back and have a few questions for you.

The final witness, and we thank you for being here. Michael Kurland is the Director of Student Health Services at the University of Connecticut. We know that college campuses have been an area in some cases where there has been an outbreak of H1N1. The Coast Guard Academy had one here earlier in the year, and then some other campuses around the country have been really quite severely impacted.

So I will be interested in hearing what you are doing and also to what extent you are reacting to what you have learned from your colleagues at the other campuses that have been more impacted. But thank you for coming.

**TESTIMONY OF MICHAEL KURLAND,<sup>1</sup> DIRECTOR, STUDENT  
HEALTH SERVICES, UNIVERSITY OF CONNECTICUT**

Mr. KURLAND. Thank you so much for letting me speak. The message I am really going to convey is that the key strategy in dealing with any type of H1N1 preparation is collaboration and partnership among many university departments, the Connecticut State Department of Public Health, local health districts, Centers for Disease Control and Prevention, Department of Education, and the American College Health Association. So it is a team effort, and we are partnering with parents and with students.

The University of Connecticut has a Pandemic Flu Continuity of Operations Committee, which follows an operational plan based upon the National Incident Management System (NIMS) model. The committee is comprised of representatives from a number of departments throughout the university, including Student Affairs, Student Health Services, Facilities, Academic Affairs, Public Safety, Environmental Health and Safety, Human Resources, the Office of the Attorney General, the Office of Communications, Finance, our regional campuses, and experts in emergency preparedness from our continuing studies area.

The committee has been meeting for the past several months in order to plan for all aspects of the health, safety, and continuity of operations in the event of an H1N1 flu outbreak. The committee is chaired by Major Ron Blicher, who is sitting directly behind me. He serves as the incident commander, and in my capacity as director of Student Health Services, I serve as the operations section chief.

Additionally, the Division of Student Affairs maintains an H1N1 task force, which has been meeting weekly in order to operationalize plans for the health and safety of students and staff. This task force is comprised of representatives from Student Affairs, Student Health Services, Residential Life, Dining Services, the Office of Student Services and Advocacy, and Wellness and Prevention Services. Meetings have included staff from Environmental Health and Safety also.

The issues that we have been addressing include but are not limited to the following: Prevention strategies in community education. The university is embarking upon a multifaceted health communications campaign in order to help prevent the transmission of the H1N1 virus. The focus is on respiratory etiquette, social distancing, proper handwashing, staying healthy, proper cleaning of personal and work space, and encouraging students and staff to self-isolate if they are infected with the flu.

The methods of dissemination of information include bulletin boards, pamphlets, table tents, curriculum infusion, mass e-mails, letters, use of a dedicated H1N1 Web site, training of staff, cable TV, and radio PSAs.

The Web site includes many helpful links as well as frequently asked questions pages for both employees and students. Additionally, students have been encouraged to be prepared and to purchase supplies of hand sanitizer, fever reducing medications, fever thermometers, and surgical face masks. Hand sanitizer has been

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<sup>1</sup>The prepared statement of Mr. Kurland appears in the Appendix on page 246.

made readily available in many public areas of the university and has been disseminated to students by many departments throughout the university.

Isolation and support services: The key to preventing transmission is to encourage isolation of sick people. I might add, UConn has over 20,000 students and we have 12,400 students living on campus. Students who are ill are encouraged to call an advice nurse to seek medical assistance for the flu. They are provided with an assessment via the phone and are requested to visit the Student Health Services, only if medically indicated, in order to avoid burdening the healthcare system and to reduce potential virus transmission.

They are encouraged to remain isolated if they do not share a bedroom with another student. If they share a bedroom with another student, they are asked to return home if their family lives within driving distance. Fortunately, 85 to 90 percent of UConn students live within driving distance of our campus.

If it is unfeasible for a student to return home, the university has designated a number of beds to provide isolation for these individuals. Students who are self-isolating or have been moved to an isolation area are provided with meals delivered from dining services, and are provided with a limited supply of flu kits and supplies such as Tylenol, Advil, fever thermometers, and surgical face masks. If medically indicated, they will be admitted into the infirmary unit (or inpatient unit) of the Student Health Services facility.

In terms of academic consideration, in order to reduce the transmission of H1N1, students are advised to be absent from classes if they have the flu. Professors have been advised to not require medical excuse notes and to expect higher than normal rates of absenteeism. Additionally, professors have been encouraged to utilize Web-based course tools which can assist students in keeping up with the curriculum in the event of illness.

Vaccination is also very important. Students are encouraged to receive both the seasonal flu vaccine as well as the H1N1 vaccine. Seasonal flu vaccine clinics have already been scheduled. They are going to be earlier than usual. We are going to have them next week. H1N1 vaccination clinics will be scheduled as soon as the vaccine is available. Doses of H1N1 have already been requested through the Department of Public Health and will be provided free of charge to all students who fall within the target groups, defined by the Centers for Disease Control and Prevention.

As I mentioned previously, we have had coordination with many outside resources. The university has been in close contact with the Connecticut Department of Public Health and has coordinated with the Eastern Highlands health district, which is one of those 41 health districts that was referred to earlier. And they are the local health department for our local 10 town area.

Now, the current status at UConn, as of this week, we have been very fortunate. We only have one confirmed case of H1N1, two probable cases of H1N1, less than 20 cases of influenza-like illness. We are, of course, monitoring the situation closely as we know it can change at any time.

Some of the challenges that we face are maintaining an ample number of isolation beds as the university residents halls are at 100 percent capacity, so there is no swing bed space.

Another challenge is maintaining continuity of operations in the event of large numbers of employee absences. UConn is its own little city. We have a sewage department. We have dining services. We have a police department, a fire department, and a payroll office. You name it, they are all essential, and we need to maintain continuity of operations.

Another challenge is maintaining an adequate amount of supplies to care for those who are sick with the flu. They are not really readily available. There are back orders on a number of the supplies. Also, deciding when to cancel public events or classes due to a large number of cases of the flu; there is no magic number. It is a challenge.

Another challenge is staffing H1N1 vaccination clinics for an unprecedented number of inoculations. If all 20,000 of our students on the Storrs campus decide to get an inoculation, that is a lot of people to vaccinate with limited staff. And then, the last challenge is the cost of supplies and personnel to accommodate the outbreak. It is not cheap.

Thank you very much for allowing me to speak.

Chairman LIEBERMAN. Thank you. Let me ask you a few questions. I am interested in the idea of telling students who live within driving distance to go home.

Does the university define driving distance?

Mr. KURLAND. That is a great question. My definition of driving distance and other people's definition of driving distance may not be the same. But two to three hours would be a reasonable driving distance. We have had students from New Jersey already go home, students from Massachusetts and Maine.

The key thing is they cannot drive themselves and they cannot go on public transportation.

Chairman LIEBERMAN. Right.

Mr. KURLAND. So it really needs to be a family or friend.

Chairman LIEBERMAN. That seems like a reasonable rule, taking any student from Connecticut and then from the surrounding States as well.

Do you think that the students are taking the H1N1 pandemic seriously, in the sense that if vaccines become available, there really will be a large demand among the UConn students?

Mr. KURLAND. I would hope so. I know the students are very knowledgeable. Massive information campaigns are out there, at the State level, at the Federal level, and at the university level. I know they are aware of the precautions. Whether they are taking those precautions, time will only tell. But they have found at a number of universities that cases have begun to spike after the sorority and fraternity rush and other large events that do not promote social distancing.

I would hope that most students would avail themselves of the vaccine when the vaccine is readily available because they are in the target risk group of those up to age 24.

Chairman LIEBERMAN. Well, that is an important point.

Mr. KURLAND. In Connecticut, the median age of people who have contracted H1N1 is age 14, so it is a much younger population.

Chairman LIEBERMAN. So the small number of cases is good to hear but do you have it at UConn now?

Mr. KURLAND. Right.

Chairman LIEBERMAN. But I presume there were more in the spring?

Mr. KURLAND. No. We had no confirmed cases in the spring.

Chairman LIEBERMAN. Oh, that is great; a healthy population up there.

Mr. KURLAND. No, lucky.

Chairman LIEBERMAN. They do not call them Huskies for nothing. [Laughter.]

Mr. KURLAND. If you were to look at a map of—and Dr. Cartter probably would have explained it. But the flu moves up from New York City. It started in Fairfield County. By the time it got to Windham and Tolland County—

Chairman LIEBERMAN. That is interesting.

Mr. KURLAND [continuing]. It was later in June. So we were just lucky because we graduated them and sent them home before they could get sick.

Chairman LIEBERMAN. Yes, great.

Ms. Wright, tell me about what you understand to be the role of the schools in a vaccination program once the vaccines become available?

Ms. WRIGHT. Since the Public Health Department does oversee the 39 school nurses, once the vaccine does become available to the student population, we have every intention of going into the school district and taking care of Waterbury students.

I am not sure what other directors of health are doing. Their pandemic flu plans, I believe, are due the first week in October, so everyone is starting to talk about that now. But we have been talking with the mayor's office and the superintendent of schools.

Our biggest obstacle that we need to overcome is we need to develop maybe a team of nurses. We cannot utilize the school nurse that is in the building. Our middle school nurse might see 110 students a day, so you cannot pull her. And our hope is to go from classroom to classroom to keep it more organized and really try to keep the educational continuity the same.

Chairman LIEBERMAN. Interesting. So what you will do then is to bring some nurses on—

Ms. WRIGHT. Bring a team of nurses to each school. And our middle and our high schools are our largest populations, of over 1,200 students, so we will probably take a much longer period of time in those buildings in terms of dates.

Chairman LIEBERMAN. Right.

Ms. WRIGHT. And then we are hoping that the elementary schools, the private, and the parochials, some of which are about 200, will be a little bit easier for us.

Chairman LIEBERMAN. I presume that the Public Health Department of a city like Waterbury would be a natural place for the distribution of vaccines generally to vulnerable populations. In a week

and a half or two, we expect the first wave of vaccines that you heard today, when the nasal spray comes available.

What are your plans about how to handle this?

Ms. WRIGHT. Well, our guidance will come from the State Health Department in terms of where the vaccine will actually land once it hits Waterbury. But we are talking to our medical providers, and the medical providers are now signing up to be vaccinators.

We will help them if we need to. We put ourselves out there as the Public Health Department to hold public health clinics. And again, our flu plans are all due, so once we start putting things down in writing—and once we really have to figure out how many vaccines are coming to Waterbury because that is going to depend on where our push is.

Chairman LIEBERMAN. So you will be the point of distribution for Waterbury to private providers; is that right?

Ms. WRIGHT. We probably will be, but, again, that guidance has to come from—

Chairman LIEBERMAN. It is not clear. But you will certainly be one of the points of distribution for people who come in and show that they are in one of the vulnerable or priority populations, and you will give them the vaccine right there.

Ms. WRIGHT. Yes. We are hoping that they do stay with their private provider. Their private provider actually knows their medical history and will be able to interview them much better than we will. They will have their medical record. But in the event that they cannot, then, yes, we hope to—the health department always views itself as the last safety net, and we hope to definitely do that.

Chairman LIEBERMAN. Good. Mr. Aloï, just a couple of questions for you. I was fascinated, if I heard you correctly, that one-third of the Aetna workers in the State telecommute or work by telephone all the time or part of the time?

Mr. ALOI. Nationally, yes.

Chairman LIEBERMAN. Nationally. So it may be a little off for that in Connecticut, but that is the national number.

Mr. ALOI. Right. We invested very wisely a few years ago in a very robust backbone of infrastructure that can take connectivity from home teleworkers through the Internet. So we can accommodate almost our entire staff that way if we had to. So one-third has already transitioned to telework.

Chairman LIEBERMAN. That is impressive.

Mr. ALOI. Yes, we are one of the leading companies in this area, and we are finding very good results from happiness in employees, productivity, saving of money for travel, all kinds of benefits from it. And it just happens to help us a great deal for this threat.

Chairman LIEBERMAN. So in this case, if you have somebody who is showing the symptoms of H1N1 flu, you can ask them to telecommute for a while.

Mr. ALOI. Well, if they are showing symptoms, we are going to send them home because we do not want them in the workplace.

Chairman LIEBERMAN. That is what I mean. You are going to send them home.

Mr. ALOI. Once they get better, then a decision will be made 24, 48 hours, whatever, to bring them back.

Chairman LIEBERMAN. I presume it takes some kind of capital investment, or does it, to enable a worker to work from home?

Mr. ALOI. Yes.

Chairman LIEBERMAN. So if a worker was going to be out 3 or 4 days, it would not be worth it?

Mr. ALOI. Right.

Chairman LIEBERMAN. I got you.

Mr. ALOI. The group I was talking about that we would send home would be—and this is some of the things we are looking for, for the triggers, is that once it is so significant and so severe in any given area, we are going to go to the next level, which is, as I said, the social distancing. And part of that social distancing is to send as many of those critical workers home because we know that, sooner or later, their children are going to be at home and they are not going to be able to come to work due to that. And also it will help minimize the spread in the workplace because you have a lot less folks there able to communicate it to each other. So we can go to the next level if we have to.

Chairman LIEBERMAN. A question about a different kind of Aetna relationship to this.

Ms. Polansky talked about the obvious problem with a working parent—let's say two working parents—when a child is sent home from school.

Has Aetna adjusted its policies in any way to deal with that, particularly if the H1N1 becomes more prevalent than it is now?

Mr. ALOI. It behooves us to accommodate workers that are encumbered by sick loved ones at home because they are more apt to be able to at least spend part of the day at home working for us versus losing their whole day of productivity. So they also would be prioritized up front for the first wave of folks to be sent home and set up pretty rapidly. We can do that in about 24 hours on average.

Chairman LIEBERMAN. Is there a company policy that shows some leniency toward parents that have to go home and take care of a sick child?

Mr. ALOI. There will be a filtering process. Those that are predisposed to a high risk group, of course, that have not received the vaccine, we would want to make sure they get home, and that is going to minimize their risk. Then next is a mission-critical worker.

Chairman LIEBERMAN. Let me ask you the broader question because obviously Aetna is a big business and in some sense, therefore, has the capacity to invest in systems like this, and also happens to know the area because it is a health insurance company.

I asked you earlier and you mentioned that you are doing some work with business customers, advising them about this. I am thinking particularly of smaller businesses

What is your impression of how they are handling the potential for a spread of this pandemic?

Mr. ALOI. We get a lot of questions from customers, big and small, on recommendations on how they should prepare because they see us as one of the experts in the field. We have to that end created messaging on our sales Web, which are our account managers who communicate with our customers. And also we have provided policies and recommendations on employer preparations, and

then also linked it over to CDC and other federally available guidance that we use ourselves, which is the CDC recommendation on business preparation. So we push them in that direction.

Chairman LIEBERMAN. So that is very good. Are you affirmatively sending out guidance to the business customers?

Mr. ALOI. Yes, we are. And we also, as I said earlier, make our course available, the handwashing and the good practices. It is an online course. It only takes about 10 minutes. We have made that available, free of charge, to all our customers.

Chairman LIEBERMAN. Are people using it as far as you know?

Mr. ALOI. Yes. We are getting pretty good hits, especially when April occurred; everybody went back and re-took it that had taken it in 2006.

Chairman LIEBERMAN. That is great.

I have no further questions. You all have been extremely helpful. I must say I am impressed by how our society gears up, governmentally, but also in a lot of different private ways, including by an active parent, to deal with the problem. And I think it is part of the reason, though we never know, why we are prepared to inhibit the spread of this as we go through this second wave.

As the earlier panel said, and we all know, we have to remain flexible and ready because this could take a lot of twists and turns before it is over, and a lot of people's health and, worse, lives will be on the line.

I really thank you for coming in. It has been very helpful. I leave here reassured by our state of preparedness, not with any superior knowledge about what path the influenza will take, but that in many ways we are prepared. And also, in the broader sense that I said this, every time we get ready to deal with something like H1N1, we also prepare ourselves to deal better with other kinds of public health or natural or unnatural disasters, like terrorist activities, so that is encouraging in all those ways.

We will leave the record of this hearing open for 7 days. If there are any further questions or statements—you may want to add to your statements. Others on the panel may want to ask you a question; even I may want to ask you some questions in writing. But, again, I thank you. It is good to end a hearing feeling encouraged about our state of preparedness.

The hearing is adjourned.

[Whereupon, at 12:15 p.m., the Committee was adjourned.]

## H1N1 FLU: MONITORING THE NATION'S RESPONSE

WEDNESDAY, OCTOBER 21, 2009

U.S. SENATE,  
COMMITTEE ON HOMELAND SECURITY AND  
GOVERNMENTAL AFFAIRS,  
*Washington, DC.*

The Committee met, pursuant to notice, at 9:36 a.m., in room SD-342, Dirksen Senate Office Building, Hon. Joseph I. Lieberman, Chairman of the Committee, presiding.

Present: Senators Lieberman, Carper, McCaskill, Tester, Burriss, Kirk, Collins, McCain, and Bennett.

### OPENING STATEMENT OF CHAIRMAN LIEBERMAN

Chairman LIEBERMAN. Good morning. The hearing will now come to order. We have called today's hearing to discuss measures that are being taken to manage the spread of the H1N1 influenza virus, which reached pandemic proportions this summer and continues to claim new victims every day, especially among young people.

I want to thank Homeland Security Secretary Janet Napolitano, Health and Human Services Secretary Kathleen Sebelius, and Education Secretary Arne Duncan for being with us today. These are the three Federal officials who have really been coordinating the Federal Government's and our Nation's response to this public health challenge—I would call it now a "crisis"—and we very much appreciate that you made the time to be with us here today for this oversight hearing.

Each of your agencies has critical responsibilities for dealing with the H1N1 public health emergency that has already taken the lives of thousands and thousands of people across the globe. Here in the United States, the Centers for Disease Control and Prevention (CDC), I gather, are no longer counting cases because of the difficulty of staying on top of the increasing numbers and confirming those numbers. But we do know that at least 2,300 people have died in the United States from the H1N1 flu in the last few months.

Under existing Federal Government emergency protocols, the Department of Homeland Security (DHS) is the overall incident manager, coordinating resources across the Federal Government and assisting State and local governments in their response to the H1N1 virus. The Department of Health and Human Services (HHS), including the CDC, has been responsible for leading the public health and medical response. And because this H1N1 outbreak poses greater risks for children than the traditional flu, the

Department of Education has helped guide local districts on how to protect their students, under what circumstances to close schools, and what to do if a school must be closed.

This particular strain of influenza—H1N1—has moved with alarming speed and taken an exceptionally high toll at a time of year when we do not normally encounter significant cases of flu. The CDC reports that the H1N1 flu has spread to all parts of the country, with almost all States reporting widespread or regional outbreaks.

I want to draw your attention to this chart that my staff has prepared.<sup>1</sup> It is actually from the CDC, and we have blown it up. It gives you a sense—the three lines chart—of the course of the flu outbreak over the preceding three seasons. This is what you might call normal flu, seasonal flu, and you can see that the spikes occur in January, the highest being 2007–08. It went way up here. We are in October now, of course, and these lines all go down to a low point, except for the red line, which is the H1N1 outbreak, which is now, at a time of year that is normally low in terms of flu impact, higher than the regular flu was at its peak in January. Of course, this raises real concerns for us about where this line will go in the months ahead.

Alarmingly, what we do know is that young children are at very serious risk, with 43 pediatric deaths tallied so far—11 of which occurred just the week before last, the most recent period for which we have data. These pediatric mortality statistics for H1N1 flu are already equal to what we usually see over the entire course of a normal flu season for children. Presumably, and regrettably, these numbers will climb higher as the outbreak shows no signs of waning.

Pregnant women are also being hit hard by the flu. Of the 100 pregnant women who required intensive care through late August, there were 28 deaths. The CDC, obviously, is concerned about that.

Thus far, the Federal Government, I will say to the three of you Secretaries and your agencies, have responded aggressively and I think as effectively as possible to the threat of the H1N1 virus. You have quite skillfully tracked the spread of the disease and who it is afflicting. You have worked with private sector partners to pull off what to us non-science majors looks like a miracle, which is to develop a vaccine quickly. You have provided important information to guide State and local officials through perils they may face as the virus escalates. And you have remained very publicly accessible and visible, communicating critical developments in this public health emergency to the American public.

I presume that previous presidential directives and national strategies for infectious diseases and influenza pandemics that were issued over the last several years informed and in some sense facilitated your decisions, which proves again the immense value of planning. So there is a lot that should be reassuring and encouraging to the American people.

I want to say frankly to you this morning that I am concerned, as we meet this morning, that the flu is spreading so rapidly and

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<sup>1</sup>The chart submitted for the Record by Senator Lieberman appears in the Appendix on page 251.

in some cases with such intensity that it may well be getting ahead of the Federal Government's ability and the public health system's ability to prevent and respond to it. And I want to give you three reasons why I have these concerns and, of course, ask you to respond during your testimony.

First, the schedule for the production and availability of vaccine—whose existence was really quite remarkable—has slipped. The 28 million to 30 million doses that will apparently be available by the end of the month is 25 percent below initial governmental projections of the 40 million vaccines that you thought would be available by the end of October. And there are now very unsettling reports of growing vaccine shortages that are leading a lot of people to ask us, and we are asking ourselves, if enough vaccine will be produced in time for all who will need it as we continue to experience the spread of H1N1 flu.

This week, one television reporter used the term “quiet desperation” to describe the feeling of public health officials around the country facing shortages of the H1N1 vaccine in their areas, and I am sure that is as unsettling and unacceptable to you as it is to the rest of us.

Second, I want to express my concern that hospitals and Public Health Departments do not have the capacity to care for the surge of people who may need hospitalization as a result of the spread of the virus. And here I am going to refer to a recent report—and this is not a stunning new problem. We have worried in terms of this pandemic—and, of course, the concern that this Committee as the Homeland Security Committee has generally—about the capacity of our public health system, for instance, to deal with the consequences of a bioterrorist attack on the United States.

I want to quote from a report this month from the Trust for America's Health that found that 27 States, including my own State of Connecticut, could exceed or come close to exceeding available hospital bed capacity during the peak of the outbreak if 35 percent of the American people become infected with the flu, which the Trust says is a plausible number. Just to make it more explicit, based on the 35-percent modeling scenario, more than a million people in Connecticut could develop the H1N1 virus, which would result in more than 17,300 hospitalizations at the peak of such an outbreak, which is about 150 percent of the total hospital bed capacity in Connecticut. I am sure that situation repeats itself in other States and throughout the country. So that is my second concern.

The third is about the availability of intravenous antiviral medications to treat people who are critically ill with the H1N1 virus. Secretary Sebelius, you have an encouraging but general sentence in your prepared testimony about this. And here I want to go from a report by the President's Council of Advisors on Science and Technology (PCAST), which posed a plausible scenario in their case in which 30 percent of the population would be infected with the H1N1 virus, resulting in almost two million hospitalizations. But what particularly struck me is their estimate that between 150,000 and 300,000 of those hospitalizations could be so serious that they would require intensive care treatment, Intensive Care Unit (ICU) treatment. A lot of those people, from what I have heard from doc-

tors, are probably not going to be able to be treated with the existing antivirals, such as Tamiflu and Relenza. The encouraging part of this story—and I want to ask, to the extent you can this morning, Secretary Sebelius, to tell us about it. I know that HHS under the Biomedical Advanced Research and Development Authority (BARDA) program, which Congress adopted and the President signed a couple of years ago, has actually been very farsighted about this and invested some money in some breakthrough work that is being done to develop intravenous antivirals for those who are critically ill with this flu. But this is one of those moments that poses a public health, also a kind of ethical, moral dilemma because I gather that they have not fully completed all the trials, but at least one of them appears to be moving along, and it is under the capacity that the Food and Drug Administration (FDA) has to grant compassionate usage authorization. These intravenous (IV) antivirals have been used in some critical cases, and I gather generally, though not in every case, have saved the lives of some people who their doctors at least thought would have died otherwise. So I want to hear from you and probably will ask you about the state of development and of decisionmaking about the availability of those intravenous antivirals.

Bottom line, the three of you, your departments, and all who are working with you have worked very aggressively and to the best of your ability. It is just my concern as we meet this morning that this flu, the H1N1 virus, is moving very rapidly. And while it seems to still be affecting most people mildly, it is clearly affecting a small percentage, but nonetheless a significant number of people, quite seriously. And so, I repeat, I am worried that the virus is getting ahead of the public health system's capacity at this moment to prevent it and respond to it, particularly with adequate treatment. So it is in that spirit that I thank you for being here, and I very much look forward to your testimony.

Senator Collins.

#### **OPENING STATEMENT OF SENATOR COLLINS**

Senator COLLINS. Thank you, Mr. Chairman.

By now, everyone in this room is familiar with the threat that we currently face from the H1N1 virus. This oversight hearing is important, however, because we must continually assess the effectiveness of Federal, State, and local efforts to respond to this pandemic, which appears to strike pregnant women, young children, and young people with particular ferocity.

Just this past week in Maine, Bates College made the news when the number of H1N1 flu cases jumped from 6 to 160 in less than a week. As of yesterday, 245 Bates students are infected with H1N1.

Public health experts are learning as they go along, sometimes with surprising results that run counter to their earlier assumptions about H1N1. For example, the CDC just released a report that found that 46 percent of 1,400 adults hospitalized with H1N1 were healthy and did not have underlying chronic illness before they got sick with the flu. While this was a preliminary analysis, the new report paints a different picture than previous studies, which had concluded that the vast majority of H1N1 patients who

became severely ill had chronic or other underlying health conditions. New data like this report must constantly be taken into account as we handle our Nation's pandemic flu.

It is clear that much work and preparation has gone into preparing for this outbreak. Our country has mobilized as government officials at all levels, doctors and other health care professionals, nonprofit organizations and private businesses have devoted significant time and resources to tackling the many challenges posed by this virus. Principals in the State of Maine have told me that virtually every school in Maine has a plan for dealing with the pandemic flu.

The Post-Katrina Emergency Management Reform Act of 2006, which was written by this Committee, mandated comprehensive and coordinated disaster planning to improve our preparedness and response for both man-made and naturally occurring catastrophes like this pandemic. In addition, Congress has allocated nearly \$9 billion to HHS alone over the past 5 years for pandemic preparedness. These efforts have laid a strong foundation for the response that we have seen to date.

Nonetheless, while the government and private sector have accomplished a great deal, significant concerns remain. For example, despite the repeated assurances of Federal officials, millions of Americans nevertheless remain worried about the safety of the vaccine. They want to know if it is safe to give to their children, what kind of testing was done, and whether it contains any dangerous additives. The State CDC in Maine reports many calls from citizens asking these questions.

State officials also remain concerned about whether there will be a sufficient number of doses of the vaccine. In the next 8 weeks, the State of Maine is scheduled to receive only 340,000 doses of the vaccine. This falls short of the amount needed to vaccinate everyone in the priority groups that the CDC has identified.

Like the Chairman, I am very concerned about recent reports on inadequate supplies of the vaccine. The CDC has been telling us since last September—or since earlier this year that the Federal Government had purchased 250 million doses of the vaccine, of which 40 million would be available by the end of this month. It now appears, as the Chairman indicated, that production delays will result in 25 percent fewer doses than had been projected for October. This disturbs us because we are seeing such an early peak in the flu.

Another issue is whether or not we have a sufficient supply of pediatric formulations of the antiviral medication Tamiflu. That is particularly important since the virus disproportionately affects children. There are also reports of phony Tamiflu being sold over the Internet.

Another significant concern that the Chairman has raised and that I share is whether or not our Nation's emergency rooms have sufficient capacity to cope with a massive influx of sick patients if the pandemic worsens.

The fact that three Cabinet Secretaries are here today demonstrates the seriousness with which the Federal Government is preparing for and responding to the H1N1 pandemic. I look for-

ward to hearing from our witnesses, particularly on the issue of shortages of the vaccine. Thank you, Mr. Chairman.

Chairman LIEBERMAN. Thanks very much, Senator Collins.

We will go to Secretary Napolitano first. Just to say for the record, this Committee has a particular interest in this oversight hearing because we are the Homeland Security Committee. Secretary Napolitano regularly is in contact and works with us, of course, and she is the incident manager for this response with overall responsibility.

And I would just repeat very briefly that this Committee was given homeland security jurisdiction in response to September 11, 2001, and the concern of raising our defenses to terrorist attack, but also, of course, to prepare for natural disasters and threats such as this one. So I thank you for all your good work in that regard and welcome your testimony now.

**TESTIMONY OF HON. JANET A. NAPOLITANO,<sup>1</sup> SECRETARY,  
U.S. DEPARTMENT OF HOMELAND SECURITY**

Secretary NAPOLITANO. Well, thank you, Mr. Chairman, Senator Collins, and Members of the Committee, for the opportunity to update you on the steps we have taken Americans for the H1N1 flu.

In April, I testified before this Committee that DHS and our Federal partners were addressing this situation aggressively and collectively. That was true then; it is true today.

As you note, Mr. Chairman, under Homeland Security Presidential Directive 5, the Department of Homeland Security is the lead coordinator, but we work with our Federal partners in a very close way. We have actually been joined at the hip over the past months. The Department of Health and Human Services, of course, with the CDC is the lead on issues related to the public health and vaccine. The Department of Education, as you note, under the leadership of Secretary Duncan, is the lead with respect to our schools and our young people. But there are many other departments of the Federal Government that you could have at this table that have been working with us in planning for the flu, and let me just note that our planning has assumed that there would be some gap period between when vaccine would be commonly available and when the flu would actually be present. In other words, we have assumed a lag time between the flu spiking and vaccine availability. So if you were to look at the planning, you would see that was built in.

In addition, we are working with State, local, and tribal partners on their planning and prevention issues, and, importantly, we are working with the American people. They are really our most important partners here. Communicating the message about how they can just by very simple actions, like washing hands and coughing properly, help slow the transmission of this virus.

Let me, if I might briefly, update you on the activities since April.

First, there has been, as noted, extensive Federal interagency work and planning that has gone on. We have been working on preparation and response actions. We have been making sure that

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<sup>1</sup>The prepared statement of Secretary Napolitano appears in the Appendix on page 255.

mission-critical, mission-essential functions could continue to be performed. We have clarified workforce protection steps, and we have been in constant communication with key stakeholders—State and local governments, the public, our employees, and the like.

We are also coordinating planning across the Federal Government for continuity in case, in light of this pandemic, we really see a surge in absenteeism as well as a surge of entrants into our health system. The Federal Emergency Management Agency (FEMA) has been coordinating that planning. They have now reviewed continuity plans for all Federal agencies and conducted 30 training sessions over the summer in terms of continuation of operations and continuation of government during a pandemic. We call that COOP and COG, but that is really what it is about: How do we work our way through this and make sure the business of the country continues?

We have—and this goes to your point, Senator Collins, about the need to continually update data—deployed a common operating picture. It is updated. It is a Web-based tool. It collects all data around the country of all different types and provides that data both to the government and to the private sector. I myself get an update at least once a day from the common operating picture about what we are seeing on H1N1 across the country.

We have clarified issues about workforce protection. This was one of the areas that was unclear in the spring outbreak of the disease, and we have provided guidance to employees based on the best science available as to what needs to be done and on human resources flexibility, personal protective equipment, and the like. And all of this guidance, by the way, is available on our Web site.

I mentioned State, local, and tribal governments. We have through FEMA provided training to 56 Incident Management Assistance Teams (IMAT). These teams are designed to be available should a State or locality say, “We need help.” The surge in H1N1 we are seeing is beyond what our own planning has accommodated or accounted for and our own personnel can handle. Those IMAT teams are on the ready, and we also have a national team. The Office of Intergovernmental Programs at the Department has bi-weekly calls with all State homeland security advisers.

One of the lessons learned from this spring, Mr. Chairman, was that we had a pretty robust homeland security communications system here, and HHS had a very robust system of communicating with public health directors, but they were not communicating with each other oftentimes at the local and State level. Lashing those things together has been one of our efforts over the summer, and it is going to be not only one of the lessons learned, but one of the improvements made in light of the H1N1 epidemic.

Over the course of the summer, the Department, with HHS, the Department of Education, and others, has released updated guidance for schools, for small businesses, for others affected or impacted by the flu, by this new strain, so they can do their own planning.

We have also been engaged in private sector outreach. We have released, with the Department of Commerce, updated private sector guidance. We also have been meeting with critical infrastructure and key resource leaders, again, under the theory that we

could have a surge before everyone is vaccinated, and we need to keep the business of the country moving with particular attention paid to critical infrastructure. So it is basic things: How to ensure continued operations, ways employees can protect themselves, human resources steps companies can take during a severe pandemic. And there have been daily update calls over the course of the past weeks, particularly with our key private resource partners.

Last but not least—it was not mentioned in either of your statements, but we did talk about it in April—is the international aspect of this, particularly with response to Mexico and Canada. Suffice it to say that we have been working with both of those countries. The Deputy Secretary was in Mexico City just 2 weeks ago to meet with our Mexican and Canadian counterparts to review emergency information sharing, communications, and issues with respect to our borders.

Through this all, we have been, as I said earlier, making assumptions that we will work our way through this flu epidemic over several months, and during part of that time, the vaccine would not be commonly available.

With respect to the surge issue in the health care arena, while the Secretary of Health and Human Services, Secretary Sebelius, will address a lot of the vaccine and public health issues that are of concern at today's hearing, let me just share with you that there has been at least \$3 billion shared with hospitals throughout the country to do surge planning. And not only that, we know from our own review of what is going on in States and localities that many health providers across the country have plans, for example, if necessary, to handle patients outside of the hospital, outside of the emergency rooms (ERs), so that the actual acute care is reserved for those who are most in need of it. And it can be anything from in some cities actually doing some triage in tents, should they need to. Houston and Kansas City are two examples of that. In Albuquerque, New Mexico, they are using an old cancer center as a place to handle flu patients during the course of the height of this pandemic. So a lot of that sort of surge planning has gone on.

Let me close in just a moment and thank the work of this Committee and my predecessors at DHS. They had done a lot of the groundwork on pandemic. We have taken that many steps forward in light of the different nature of this flu. It is not the same as avian flu. It has different issues with respect to homeland security planning, but, nonetheless, we worked from a basis that was quite well done.

Chairman LIEBERMAN. Thanks very much for that testimony, Madam Secretary.

Secretary Sebelius, welcome and we look forward to your testimony now.

**TESTIMONY OF HON. KATHLEEN SEBELIUS,<sup>1</sup> SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Secretary SEBELIUS. Thank you, Mr. Chairman. Chairman Lieberman, Ranking Member Collins, and Members of the Com-

<sup>1</sup>The prepared statement of Secretary Sebelius appears in the Appendix on page 266.

mittee, I am pleased to have a chance to appear with my colleagues and give you an update at this critical time. And I would start by echoing what Secretary Napolitano has said, that the collaboration and cooperation of not only the three of us representing three critical front-line agencies but across this government has been remarkable, and we have had wonderful results also with State and local partners, tribal partners, the private sector, and others. There is no question that we would not be where we are today without that collaboration.

I wanted to point out to the Committee Members that you have, I think, packets at your desks which have a couple of important pieces of information. We believe strongly, as the President indicated from the outset, that we should be guided in our response by the science, and CDC is our lead agency for the science-based advice. Dr. Anne Schuchat, who is with me today, has been widely available, but what I have given to Committee Members is a situational update as of October 21. These updates are now being done twice a week by CDC to give you an overview. We have some information that gives you some ideas of the kinds of things we have been putting forward for business and employers and the private sector, and then some examples of what is on flu.gov. And, Mr. Chairman, I would tell you that our flu.gov Web site, which early on was constructed as a sort of one-stop shop, is now getting 5 million hits a week. So people are using that tool, and I think that is very good news because it gives some regular detailed, scientific information on a consistent basis.

We have some good news about this flu epidemic. The virus has not changed significantly since April, and that means that the vaccine target is appropriate. It is getting a robust response. And that, again, is good news. Except for a couple of cases that seem to be outliers, the virus continues to be susceptible to Tamiflu and Relenza. That, again, is very positive that we are in a situation where the antivirals that we have are working.

No question, as the Chairman has already said, that we are seeing some very unusual activity. Flu season officially began on October 4, but as the Chairman indicated in the chart he has passed out, this does not look like a typical flu season. Visits to doctors are higher than expected. Forty-one States represent what we call now "widespread level of activity," which is just the count that they are giving, and the remaining States are at elevated levels of flu. So this is a national issue.

One of the most troubling aspects is the higher rate of illness among children and young people. There are actually 86 H1N1 lab-confirmed pediatric deaths since we began reporting this in April. And the number is equivalent to the entire flu season of past years' lab-confirmed deaths of children, so we are already at that level. And, tragically, pregnant women are also among those seriously affected.

Half the hospitalizations for flu-like illness are for people under the age of 25, very different picture than seasonal flu, and nearly 90 percent of the deaths from H1N1 are among people under 65—again, a very different picture than seasonal flu, where 90 percent of the deaths year in and year out are for Americans over the age of 65.

Those are pretty grim facts, but thanks to the work of this Committee and your colleagues across Congress, I think we are better prepared to deal with the current challenge than ever before in history.

I want to just touch on a couple of efforts that you have helped put in place.

First of all, we have a greatly enhanced surveillance system, so the numbers that we are giving you probably 2 or 3 years ago would have been anecdotal, at best. The system is very critical to monitoring what we are doing and making sure we have adequate supplies of materials and vaccine and we can have that relying on the fact that we are getting accurate numbers.

We have an expanded testing capability, again, thanks to the planning work that has been done intensely monitoring changes in the virus around the United States, but also across the world, we need to know what is happening with this virus so, again, we stay out ahead of it and using a variety of systems to do that.

The efforts improve our understanding of the magnitude and the trajectory of what we are seeing and help us stay ahead of it.

We have provided significant recommendations, working hand in hand with the Departments of Education and Homeland Security, but also Labor and Commerce, clear, actionable guidelines for businesses, for K–12 schools and universities and colleges, which the Secretary will address in a few minutes, with community and faith-based organizations, based on the best scientific information—again, it is on flu.gov, easy to print, run in multiple languages, updated on a regular basis—but trying to make sure that the information that we know in the scientific community is shared.

The vaccination program is underway, and as the Chairman and the Ranking Member have indicated, the production is slower than we would have hoped at this point. But I want to put this in a little bit of context. The virus, first identified in April, now has a robust vaccine available. That in and of itself is fairly remarkable.

We are dealing with five producers. That is a very different situation than even we were in as recently as 3 or 4 years ago, so the capacity for vaccine has been built.

As of Monday, we have 11 million doses of that vaccine ordered by the States, and those orders are being done on a daily basis. As the vaccine becomes available, States and local regions are ordering, and we are pushing them out. We are now up to 150,000 sites around the country identified by our State and local partners where the vaccine is automatically delivered, so it is not being held at points along the way.

And, Mr. Chairman and Madam Ranking Member, I would remind the Committee that when the more robust estimates were being made—and, again, these are production estimates that come directly from the manufacturers. We have not made estimates. We are relying on their numbers. We were in a situation where we anticipated a two-dose regimen, and those two doses required a 3-week gap, and then 2 weeks at the end to have a robust response. So approximately 36 days from first dose to immunity was what we were looking at earlier.

We now have some good news. Everyone over the age of 10 will need only one dose of the vaccine, and the immune response is hit-

ting at a much shorter time. So rather than 2 weeks, it is in an 8 to 10-day period. So we are getting their lower numbers available but a faster response time than we had anticipated, and with a one-dose regimen, we actually are in better shape than we had hoped with people being immunized at an earlier basis.

The vaccine early delays are really due to two issues that we have identified. One is that the antigen production was yielding lower results than had initially been anticipated. We have been assured by the producers that has been fixed, so their yields are now more robust, and those numbers are beginning to change. The second is that we have some production lines that have been put in place by the manufacturers. That is the good news. The bad news is there were glitches in some of those production lines. The fill and finish did not work as they had anticipated. We are seeing some hurdles. Again, in discussions with all the manufacturers, those two issues were corrected so we anticipate that number growing exponentially as we move through the season.

By early November, we are confident that vaccine is going to be far more widely available. There is enough vaccine and will be to vaccinate every American who wants to be vaccinated. And we are pushing it out as quickly as we can.

So I just want to mention finally a couple of lessons that we have learned in this experience. Again, thanks to the Committee, a lot of planning has been done, but we are still too dependent in the United States on vaccination production in other countries, and we are using old technology. We are still using egg-based technology. Thanks to investments through this Committee and others, we are committed to developing cell-based and newer technology, faster growth time, and that is underway, Mr. Chairman. And we need to make all aspects of the manufacturing process appropriate for the 21st Century. That does not just help our country. It really helps the entire world. So continuing to focus on those issues, I know many in this Committee have been very focused on that.

Vaccination safety is essential, and CDC and FDA monitor the safety of all vaccines. And I know in the Ranking Member's comments, there still are lingering questions. We are in a Catch-22. Where is the vaccine on the one hand, and have you taken enough time for the clinical trials on the other. We can assure this Committee, this vaccine is being made exactly the way seasonal flu vaccine is made, so we have specific clinical trials on H1N1, but more than that, 100 million people each year receive a seasonal flu vaccine, and we expect the same very positive safety results from this vaccine as we have had in the past.

In terms of the antiviral, which is, again, a question that was asked, PCAST did recommend the acceleration of an intravenous antiviral as part of the recommendation to the President. We took that very seriously. That is underway. The good news is we have encouraging results from several different candidates, and we anticipate final decisions being made by the scientists very shortly. BARDA was wise to move ahead of this pandemic and begin that process, so we are very encouraged by the results. But the scientists will lead our recommendations in terms of getting that antiviral on the market.

And, finally, Mr. Chairman, we are continuing to focus on mitigation. In the meantime, there still are some fairly simple steps that people need to take: Social isolation, staying home when you are sick, washing hands, coughing and sneezing into arms. I have been very impressed that children are listening to Elmo, and they are correcting their parents in terms of sneeze technique. And we are doing everything we can think of with our partners in terms of the communication effort, not only using traditional media, but we have great partners in "Sesame Street," in Sid, the Science Kid, where the Secretary and I will launch a new program today, and on Facebook and Twitter. ESPN that runs the score scrolls into colleges dorms is a partner in encouraging that age group to get the vaccination. We have had YouTube videos. So we are trying to get the word out to folks that vaccination is the best offense against this flu, and the good news is, I think, it is beginning to become available around the country.

And with that, Mr. Chairman, I will wait and answer additional questions.

Chairman LIEBERMAN. Thanks, Madam Secretary. Very helpful testimony. I am sure we will have questions. Also, let me express my admiration for your quite appropriate cough into your elbow.

Secretary SEBELIUS. Thank you. [Laughter.]

Secretary DUNCAN. Great technique.

Chairman LIEBERMAN. Great technique. It is not our reflex because for all of our lives, we have been trained otherwise. Also, I want to express gratitude to the staff here for the hand cleanser that has been left here.

You are not Arne, the Science Kid, are you?

Secretary DUNCAN. I am not. I wish I was. He is a lot smarter than I am.

Chairman LIEBERMAN. Secretary Duncan, it is an honor to have you here, and we welcome your testimony now.

**TESTIMONY OF HON. ARNE DUNCAN,<sup>1</sup> SECRETARY, U.S.  
DEPARTMENT OF EDUCATION**

Secretary DUNCAN. Thank you so much, Chairman Lieberman, Ranking Member Collins, and Members of the Committee, for inviting all of us to testify before you today. I really appreciate your collective leadership on this issue.

I really want to thank my partners here, Secretary Sebelius and Secretary Napolitano. The interagency coordination and cooperation in the Federal H1N1 effort from top to bottom, I think, has been absolutely extraordinary. I also want to thank our partners at CDC. Dr. Anne Schuchat, who is here, and Dr. Tom Frieden, the Director, have been great partners.

Our team at the Department of Education has been working very closely with the Departments of Health and Human Services and Homeland Security and the CDC since the initial outbreak of the H1N1 influenza in April to prepare thoughtful guidance for early learning programs, elementary, middle, and secondary schools, and institutions of higher education. We have brought copies of our guidance here, copies of guidelines for early childhood, guidelines

<sup>1</sup>The prepared statement of Secretary Duncan appears in the Appendix on page 279.

for K-12, and then, finally, information for schools of higher education. It has been an extraordinary team effort, one that I hope can serve as a model for dealing with other problems and issues that cross agency boundaries.

I want to spend most of my time this morning discussing our efforts to keep children, students, faculty, and staff safe during the fall wave of the H1N1 pandemic. And I think I want what I know every parent wants: To first and foremost keep our children safe; and, second, to keep them learning.

While I want to concentrate on our current efforts—and by “our” I mean all of our agencies together—I think it is also important to take a moment and look back to see where we were in the spring. I think you will agree that we have made significant progress in a short period of time.

In the spring, from April to June, we found that schools closely followed school dismissal guidance developed by the CDC. For example, on April 26, 2009, the CDC advised schools to consider closing when they had a confirmed or suspected case of H1N1, and we found that schools adhered to that advice.

On May 4, 2009, the CDC revised the guidance to state that schools should not close “unless there is a magnitude of faculty or staff absenteeism that interferes with the school’s ability to function,” and fewer schools closed and many that were closed reopened. From April 27 through June 12, more than 1,350 schools in 35 States closed for at least one day. These closures affected over 824,000 students and about 53,000 teachers. The greatest number of school dismissals occurred on May 5, when 980 schools and 607,000 students were affected. As school districts started to implement the new guidance on closures, those numbers rapidly declined.

The lesson we learned in the spring was not only that schools follow the CDC’s advice on flu-related issues, but also that quickly closing a school is a complex undertaking that has consequences beyond the loss of valuable and desperately needed school time. For example, unplanned school closures led to the loss of millions of school meals for children who rely on these Federal programs to eat; loss of wages for parents who had to stay home from work to take care of their children; and older students were left home without proper supervision.

Further, we learned that we had to develop a new way to better track school closures and dismissals; the way we were doing it did not work well, especially when there were a large number of schools that were closed.

Examination of our efforts during the spring outbreak helped us to understand where we could do better. In particular, we needed to improve on several things.

First, we needed to offer schools balanced, measured, clear, and concise guidance that reflects the best science available.

Second, we needed to design a tracking system that provides accurate and on-time data on school dismissals.

Third, we needed not only to continue to reach out to those we reached out to in the spring, but we needed to get to a much expanded audience. Getting the message out and making sure it is the right message, and getting it out quickly to as many schools,

school officials, and parents as possible is the key to our ongoing communication strategy.

Fourth, and finally, we needed to develop more materials for schools and educators and to develop those materials in a format that made them understandable, useful, and easy to use for schools and for educators.

Let me briefly expand on each of those points.

With regard to the first point on guidance, we knew that while in a limited number of cases school dismissals were warranted, if conditions in the fall mirrored those in the spring, schools could remain open as long as they took various prudent measures, such as encouraging educators and students to practice good hygiene such as washing hands and coughing into their sleeves, having students stay home if they are sick, and practicing social distancing such as rearranging desks so students could sit a little further apart.

With regard to the second point, we developed a new K-12 school dismissal tracking system this summer. The new school dismissal monitoring system is a collaborative effort between the CDC and the Department of Education, and it is supported by State and local health and education agencies, as well as national nongovernmental organizations. The system is built on a nationwide Federal and State partnership. The new voluntary system includes daily, direct reporting from State and local agencies as well as daily, systematic searches and confirmations of media reports.

As I mentioned, this past spring almost 900,000 students and more than 1,350 schools were impacted by school closures. This fall, however, so far schools are heeding the new guidance. School dismissals are significantly lower. In fact, between August 3 through October 15, only 628 schools closed for at least one day, affecting approximately 219,000 students. As of yesterday, just 88 schools were dismissed in 13 States affecting 28,000 students and 1,800 teachers.

In a front-page story in the *New York Times* on October 8, they pointed out that “[a]ttendance in the New York City’s public school system, with just over a million students, was 91 percent. . . . Last spring, when the virus was rampant, nearly 60 schools were closed and about 18 percent of students were absent.”

The reductions in the number of schools that closed as a result of H1N1 are a direct result of a number of things, including much improved outreach and communication.

In our effort to prepare the education community for H1N1, and to prevent the virus from spreading to a point that it fundamentally disrupts education, we have worked with our Federal partners to develop and distribute guidance for early childhood, K-12, and higher education institutions. In this effort, there is a role for nearly every major stakeholder group to play.

Over the summer, we convened a group of representatives from many of education’s major associations—those representing teachers, principals, school administrators, school boards, colleges and universities, counselors, and, very importantly, school nurses, and parents. We talked about ways that every partner could contribute to this massive preparation and prevention effort, and I want to thank all of them for stepping up and answering the call.

For instance, the National Association of School Nurses, the National Parent-Teacher Association (PTA), and the National Association of School Psychologists collaborated on a guide for parents to help them talk to their children about H1N1 and support prevention methods. Available initially in English and Spanish, that guide—and so many other useful H1N1 resources—has been translated into many other languages as well. And the school nurses association recently heard that a Japanese newspaper had translated it into Japanese.

Also, in September, HHS, CDC, and the Education Department held a call for the child-care community to discuss the steps to be taken by providers and parents of young children to keep everyone safe. We had about 800 participants on that call from around the country. We had another 800 participants on a similar call with the higher education community.

We have also been working with the business community, especially educational publishers and national companies in media and technology, to make resources available so that students can continue learning if they are home sick or their school is dismissed. Thanks to these companies' commitments, America's students will have a variety of both hi-tech and low-tech ways to stay connected to their classrooms.

As part of this effort, we have developed continuity of learning guidance, recognizing that different schools will have different ways of carrying this out depending on their situation and where they are located. In our appendix to that guidance, we cite a number of efforts by States and school districts around the country, including, for example, the Arkansas Distance Learning Development Program. While our prevention efforts must and will continue, we are now putting the full-court press on the importance of vaccinating children.

Let me say here that my wife and I certainly intend to try and lead by example by getting our two young children vaccinated at the appropriate time.

We realize that vaccinating students is the best way to ensure that the flu does not spread. We have made available for all 14,000-plus school districts an easy-to-read document that explains how schools can work with public health officials to establish or host a vaccination clinic. Also, CDC has provided a sample letter for schools to use to get parental consent for the vaccine now so shots can be given absolutely as soon as they become available. And I am delighted to say that we have seen some terrific examples of States doing this well.

For example, the Rhode Island Department of Health has made plans to operate clinics in every single school in the State, using licensed medical professionals enrolled through its Statewide Emergency Registry of Volunteers. The Public Health Department plans to vaccinate middle- and high-school students during the school day and offer after-school and weekend clinics for younger elementary school students.

In Kansas, the Sedgewick County Health Department has partnered with several local public and non-public K–12 schools in the Wichita area, as well as higher education institutions, to provide vaccines through school-based clinics.

And in Utah, the Salt Lake Valley Health Department has solicited bids from nursing agencies to provide vaccinations in schools. These providers already have demonstrated capacity for managing these large-scale efforts. Timing may vary by school but officials envision setting up clinics in large spaces, such as an auditorium, and vaccinating one class at a time those students whose parents have provided consent.

To conclude, all of these efforts will continue so that we can do our best to help schools be as prepared as they can be to handle the flu. Again, thank you so much for allowing me to testify today, and we look forward to your questions.

Chairman LIEBERMAN. Thank you very much, Secretary Duncan. Very helpful information. Obviously, a lot of parents are very concerned about this, and the schools are the significant point of daily contact.

We will do 7-minute rounds of questioning.

Secretary Sebelius, I have been following this, of course, as a parent, a citizen, and a grandparent, but also because of the Committee, and I must say this chart from the CDC really clarified how serious this has become because of this extraordinary surge now,<sup>1</sup> which is way above what typical flu activity is at this time of year, and also the reported cases and deaths.

I understand this is an unusual—it is hard to predict here, but to the best of your ability, what do we expect—in other words, this line representing the patient doctor visits has really shot up. Is it going to continue to go up? Is it going to merge with the normal increase in seasonal flu that would come around January? So, to the best of our ability, understanding that, if I may use military terms, we are facing an enemy whose movement is unpredictable, what do the experts tell you to expect so we can be prepared to, if you will, defeat the enemy?

Secretary SEBELIUS. Well, Mr. Chairman, I think you used the appropriate term in “unpredictable,” and what the experts tell me is a couple of things. We are not seeing a massive surge at this point in communities that had significant outbreaks in the spring. And if you remember what the spring looked like, it was very sporadic around the country. New York City, as the Secretaries just said, had a very significant outbreak, and two States away there was very little flu. We are still seeing the same kind of activity of hot spots in various parts of the country and others without a lot of activity.

We anticipate, though, that line will continue to rise until we can make a fairly significant dent through the vaccination programs, and that is what is very good news, that the vaccine is appropriate, it is targeted, and so continuing the mitigation efforts, which are having some impact, even the short-term periodic school closings are far less, but they seemed to quell the outbreak for a bit and go on. But getting people vaccinated is the key.

Chairman LIEBERMAN. Yes. So this is really a question of the vaccinations catching up with and moving ahead of the spread of

<sup>1</sup>The chart submitted for the Record by Senator Lieberman appears in the Appendix on page 251.

the disease because so far there has been indication that the vaccines are working, of course.

Secretary SEBELIUS. Absolutely. The clinical trials say that vaccines are right on target, and the robust response hits in about 8 days, shorter than expected, and people need one dose fewer than expected.

Chairman LIEBERMAN. OK.

Secretary SEBELIUS. So the goal is to get the vaccine out as fast as possible and get as many people, particularly, start with the high-priority groups, but get it to everyone who wants a dose.

Chairman LIEBERMAN. Right. You clarified—and I appreciate it—the fact that at the end of October we are going to have 25 percent less of the vaccine than you had predicted. Your predictions were obviously based on what the manufacturers had told you.

Secretary SEBELIUS. That is correct.

Chairman LIEBERMAN. And they simply, although as I said earlier—and I give everybody credit—they worked with remarkable efficiency to develop the vaccine quickly, but they just have not been able to produce it as quickly as they had thought.

Secretary SEBELIUS. Well, as I said, the early yields were significantly lower than they had predicted when we started this modeling in May. That has been corrected. They now have yields which are back up to where they thought they would be, so we anticipate, again, a much more robust production line. And some of the early lines, the new lines of production, particularly the fill and finish, had some early glitches, a hard rollout, if you will, that they were trying to ramp up. But those both have been corrected, and we are in daily contact with the manufacturers.

Chairman LIEBERMAN. OK. So your goal is—and you predicted, in a way guaranteed—that there will be enough vaccine to vaccinate every American who wants to be vaccinated. But am I right that there is not now enough vaccine to vaccinate every American who now wants to be vaccinated?

Secretary SEBELIUS. That is correct, Senator. Right now we are at a point where the demand is ahead of the yield, and we are working—that is why I think it has been very good news that we have a distribution contract that really gets the vaccine on a daily basis to these multiple sites, 150,000 sites. So as soon as it is out, it is being allocated on a per capita basis to States. States can order daily and they are taking advantage of that. So we have about 13 million doses available. They are being pushed to States, overnight. Every day that they come in, we are pushing them out the door.

Chairman LIEBERMAN. OK. Not for now, but I am just going to say quickly, and go on to another question, there is an important question for all of us to ponder about the fact that if I am right, of the five producers of the vaccines for use in the United States, only one is in the United States. And we have got to ask ourselves questions about what is happening that we have lost that edge, that domestic supply.

But let me go on to the more urgent question I want to ask, and that is about the availability of the intravenous antiviral medications. And as a result of the broadcast news report a couple of nights ago, there has been a lot of anxiety expressed about this, be-

cause these are the most serious cases. These are the people—again, the percentage of the population quite small, but if this is your relative in an ICU with a serious case of H1N1, facing death possibly, you want whatever science can give you to deal with this. And I gather that, again, the existing antivirals—Tamiflu and Relenza—do not work with these most serious cases.

I also understand that the FDA has issued some compassionate-use rules in a limited number of cases, as I mentioned. Some of these intravenous antiviral medications have worked and have been largely successful in saving lives. So with these extraordinary predictions of 150,000 to 300,000 cases that will require ICU placement of people, I want to push you a little bit on the status here because, truthfully, your response in your testimony was a little less reassuring than your statement in your prepared testimony. I will read it again. In your prepared testimony, you said, “Physicians treating critically ill patients with H1N1 influenza will soon have access to new antiviral drugs supported by HHS/BARDA and administered intravenously under a CDC-sponsored Emergency Use Authorization.”

I know that at a National Biodefense Science Board meeting last week, the FDA said that they will be making a decision fairly soon about the use of a tested but still experimental IV antiviral drug, and this is that power that FDA has to issue an Emergency Use Authorization before the drug goes through all the clinical trials because of the urgency.

So give us a better understanding, if you can—and I understand this is FDA’s decision—about how soon people who are in these severe situations can expect, if they choose, to have an IV antiviral available.

Secretary SEBELIUS. Well, Senator, I would tell you that it is, I think, among the highest priorities with FDA and CDC working very close together. It has been identified early on by BARDA as a need. PCAST recommended that, as we saw the outbreak, we move forward.

I would say that we are very close to having several candidates that are being tested in the final stages, and I think that it is imminent. I cannot give you a precise timetable.

Chairman LIEBERMAN. I understand, but we are really talking a matter of days.

Secretary SEBELIUS. We hope that is the case.

Chairman LIEBERMAN. Yes. And just to clarify, the FDA and you take these threats seriously enough so that what is being considered is an Emergency Use Authorization—in other words, that it will be available even though the full clinical trials have not been gone through because, for a lot of people and their families, this will be a life-and-death decision.

Secretary SEBELIUS. Yes, Senator, all of that is correct, and it is imminent.

Chairman LIEBERMAN. OK.

Secretary SEBELIUS. The other antiviral issue, which the Ranking Member mentioned, is the pediatric antivirals and the so-called pediatric suspension that is available. We have done two things with pediatric suspension, which, again, it is not in the same situa-

tion where it is in the pipeline in terms of being licensed for use. It has been licensed, but there is a shortage.

HHS took steps to push 75 percent of the stockpiles out to States, so 300,000 doses are now in the hands of State and local health officials as of earlier this week. We also simultaneously published guidelines which deal with compounding. On the ground, pharmacists can separate the pills, mix them with syrup, and have this available for children who are too young to actually take pills. And so both of those steps have been taken earlier this week. There is plenty of compounding production available throughout the country, so we have gotten the stockpiles out and the guidance about compounding and asked the manufacturer to ramp up the production of this.

As you all know, sometimes the private market is reluctant to anticipate what may be a market, which is why investments in BARDA and elsewhere have been so effective. So we are catching up. But in terms of the pediatric antivirals, I think there is an on-the-ground solution that is being taken advantage of.

Chairman LIEBERMAN. Good. Thank you. Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Secretary Sebelius, you have given us the good news today that the vaccine is effective, that it is as safe as the seasonal vaccine, but there still is an issue of whether the vaccine is going to get to people too late. You stated in your written testimony that there will be enough vaccine for anyone who wishes to receive it.

But a study that was published last week by Purdue University stated that the vaccine will arrive too late to help most Americans who will be infected. The authors of this study estimated that the greatest number of infections will actually occur this very week while most people are still waiting for the vaccine.

Are you concerned that even though we have been very successful in developing an effective vaccine that it is going to arrive too late to do the good that we would hope?

Secretary SEBELIUS. Well, Senator, we would love to have lots more available today, no question about it. I would suggest, though, that we are at the very beginning of seasonal flu, and what we anticipate is not necessarily a dropping off but a continued rise, and particularly as people get seasonal flu and it mixes with H1N1, that continues to be a concern. So we have all along urged people to take advantage of the seasonal flu shot, and, again, there is a good news/bad news about seasonal flu. The demand is significantly higher and earlier than ever before given all of the discussion about the flu, so it has caused, again, a shortage in some areas of the country. That is being made up quickly.

But we anticipate, Senator, that there are still hundreds of millions of Americans who are potential victims of the flu, who have not gotten the flu, who will be protected by the vaccine, and what the scientists are urging is even if people experienced flu earlier this spring or this fall, to go ahead and get the vaccine because, as different strains develop over the course of the flu season, it will immunize them for what is likely to come.

Senator COLLINS. The Chairman raised the issue of the fact that our country has largely lost the capability to produce vaccines, and we have to rely on companies that are located in other countries.

And it is my understanding that a major reason that we have lost that capability is because of liability concerns.

Is the Administration developing any kind of plan or recommendations to try to ensure that we have the capability to produce vaccines right here in the United States?

Secretary SEBELIUS. Well, Madam Ranking Member, the Congress invested in an entity within the Department of Health and Human Services, the Biomedical Advanced Research and Development Authority (BARDA).

Senator COLLINS. BARDA.

Secretary SEBELIUS. Which is actually, I think, a very significant entity because a lot of these vaccines are developed anticipating something will happen. So there is not a lot of private market appetite to spend money and time with development.

I would say that this vaccine development was a collaborative effort from the outset, where the scientists from FDA sat down with the manufacturers and discussed the timetable. They figured out a way to reduce the growth time. No safety steps were cut, but the production occurred as quickly as could conceivably be done from the time that the virus was identified.

And, finally, in terms of the liability issues, in the various steps to deal with pandemic efforts, you have created a liability immunity, not only for the production but every step along the way for distribution. So that has been in place for a number of years and actually was designed to address just the issue that you raise. But the legal protections have been in place I think for the last 5 or 6 years.

Senator COLLINS. Thank you.

Speaking of liability, Secretary Duncan, in Maine many school systems have stepped up to the plate and are conducting school-based vaccination clinics. But the issue of liability has arisen in the State of Maine of whether schools that administer these vaccines could potentially be held liable in the rare case that there is an adverse reaction to the vaccine. The Governor of Maine has attempted through an executive order to deal with this issue, but is this an issue that you are hearing about from school systems?

Secretary DUNCAN. It is obviously a really important question, and we are thrilled that your schools are stepping up. We want schools to be part of the solution, and with young children being such an at-risk and vulnerable population, it makes logical sense that schools be vaccination clinics.

In all likelihood, schools will not be liable, which is the good news. Schools that are being used as vaccine distribution sites are generally protected by the Public Readiness and Emergency Preparedness (PREP) Act, and this law protects school districts and their employees from liability for claims that may result from administration of H1N1 vaccine in schools. So unless someone is intentionally doing something to harm a child, they are going to be protected.

Senator COLLINS. Thank you.

Secretary Napolitano, my staff has passed me a note to say that there has been a new development with the outbreak of H1N1 at Bates College that I mentioned in my opening statement, where we have gone from 6 cases to 245 in just a little over a week's time.

And the Maine CDC has now requested that a component of the Northern New England Metropolitan Medical Response System (MMRS) deploy to the campus. And that system, as you may know, is part of DHS's efforts and it is funded through a DHS grant program to enhance the medical response in a mass casualty situation.

Are you aware across the United States of the deployment of other MMRS units?

Secretary NAPOLITANO. Madam Ranking Member, I am not aware specifically of the deployment of others, but it does not surprise me. And, with Bates College, that is a large percentage of their students.

Senator COLLINS. It is.

Secretary NAPOLITANO. But the IMAT teams, the other teams that I referenced in my formal testimony were all designed to provide back-up to localities, to States at their request when they had a particular outbreak.

Senator COLLINS. Thank you, Mr. Chairman.

Chairman LIEBERMAN. Thanks very much, Senator Collins.

As is the Committee's rule, we call the Senators in order of arrival. Just for information, that would be Senators McCain, Bennett, Kirk, Carper, Burris, Tester, and McCaskill.

Senator McCain.

#### **OPENING STATEMENT OF SENATOR MCCAIN**

Senator MCCAIN. Thank you, Mr. Chairman, and I thank the witnesses.

Secretary Sebelius, this chart is one that would cause concern. Is that an accurate description of what this chart indicates?

Secretary SEBELIUS. It is, Senator, and I was reminded by Dr. Schuchat that, in response to the question of is it too late for vaccine? Again, what we saw in 1957 was a significant outbreak in the fall, and then a die-down, and then another significant outbreak in the spring.

Senator MCCAIN. So you think that in the winter months this will come down?

Secretary SEBELIUS. Well, we are hoping that as vaccine becomes available and people get vaccinated that will at least help to stem the spread because what we are now seeing is a spread that is not mitigated by any immunity.

Senator MCCAIN. But you also just said there are millions of people who will not be vaccinated.

Secretary SEBELIUS. There may be people who choose not to be vaccinated, Senator.

Senator MCCAIN. Are you worried about hospital overutilization, lack of capacity in the hospitals in America?

Secretary SEBELIUS. Well, as Secretary Napolitano said, about \$3 billion has been pushed out over the last number of years for surge capacity. What we are trying to do is minimize the demand of the worried well on hospitals, which is why a lot of the self-evaluation tools, a lot of the information on the flu.gov Web site is trying to get people to the point where they understand they do not need to show up at the hospital unless certain situations are present.

Senator MCCAIN. So you have significant confidence that will not be a problem?

Secretary SEBELIUS. Well, Senator, I am worried about all of this, and I think we are doing everything we can to work with hospitals across the country, including an additional \$100 million that you helped to make available.

Senator MCCAIN. In your testimony concerning the availability of the vaccine, according to a news report yesterday, "Arizona will be getting only a fraction of its first orders of swine flu vaccine which could throw a wrench into health officials' plans to vaccinate hundreds of thousands of residents in coming week. So far, the State has only been allowed by Federal health officials to order about 156,000 doses of H1N1 vaccine, less than half of which has arrived, with the rest expected sometime next week. Original planning called for 800,000 to 1 million doses to arrive around next Thursday."

That is a rather significant difference from what they expected to receive in Arizona, Madam Secretary.

Secretary SEBELIUS. Yes, sir.

Senator MCCAIN. And your statement, as I quote from, "a series of manufacturing delays has caused significant reductions in the manufacturers' projected vaccine output." Maybe for the record you could tell us about these manufacturing delays and whether are they in the one facility we have in the United States or are they from our foreign sources of vaccine?

Secretary SEBELIUS. Well, Senator, as I had said earlier, the production yields are lower than what the manufacturers estimated when they first started. So with the egg-based technology there are lower yields of the antigen, and they were wrong with what they anticipated. Those yields are now up. They have changed strains. They are working now. The virus is equally robust, but they are now getting much higher production yields than first anticipated.

Senator MCCAIN. And what is your estimate as to when they will catch up?

Secretary SEBELIUS. Well, we are hoping by early November that they will be back on the track of the number of vaccination doses per week that we had originally anticipated.

Senator MCCAIN. How long would you expect a State like mine to not have the quota fulfilled that they had expected?

Secretary SEBELIUS. Senator, what is happening in Arizona and every other State is that daily orders are being made on a per capita basis, they are being pushed out the door, so as soon as it—

Senator MCCAIN. When would you expect them to be caught up?

Secretary SEBELIUS. Senator, I have no idea. I could get you that information based on—I cannot tell you when Arizona will be at the—

Senator MCCAIN. I mean all States. When will all States be caught up? Maybe you could supply that for the record. I am sure that people are concerned about that.

Secretary SEBELIUS. I will try to get that.

Senator MCCAIN. When would we have a sufficient number of vaccines necessary? I would be interested in when you anticipate for those original estimates will be met.

Secretary SEBELIUS. We can get you that number, Senator, and as you know we are not sure how many people will take it up. The seasonal flu take-up rate is below 50 percent.

Senator MCCAIN. But you did make original estimates as to what is needed, and so I would be interested in knowing when you are able to—with the manufacturing capability now restored, when we will restore to what the original requirements are.

Secretary SEBELIUS. We will get you that information.

Senator MCCAIN. Thank you.

INFORMATION SUBMITTED FOR THE RECORD FROM SECRETARY  
SEBELIUS

**What is the projected date when you believe all States will receive their requested number of H1N1 vaccines?**

HHS has now received all its vaccine orders and any American who wants to be vaccinated should be able to do so. As of March 12, 2010, States have been allocated 149,977,200 2009 H1N1 vaccine doses. Thus far, States have consistently ordered approximately 80–90 percent of the vaccine doses available to them. So there is sufficient H1N1 vaccine for all States to receive their requested amount.

**When will we have sufficient number of vaccine to make sure we do what is necessary?**

As of December 1, 2009, sufficient amounts of H1N1 vaccine (229 million doses) had been produced to serve the U.S. population and to meet international commitments for donated vaccine. As a result, production of additional H1N1 vaccine was halted.

**When will we be restored to the original requirements?**

The original estimate in the summer was that we would need as many as 600 million doses to cover the entire U.S. population. When clinical results showed that only those ages 9 and under would need two doses and everyone else one dose, the number needed was dropped to about 340 million doses. As information on uptake and public desire for the vaccine became available, the number was revised downward. By the beginning of December it was determined that 229 million doses would be sufficient.

Senator MCCAIN. Secretary Napolitano, have we still a big concern about visitors to the United States being screened for H1N1?

Secretary NAPOLITANO. Senator, we take our guidance from the CDC, and we are doing our standard screening, but we are not doing any different type of screening than we would normally, in part because this is not like an avian flu situation. This virus is already widespread through the continent.

Senator MCCAIN. So it is already here.

Secretary NAPOLITANO. If we thought screening would help the public health situation in the United States, we would do something differently. But everything we have been advised is that what we are doing is the most that can be expected, and anything else would have no practical impact on the public health of the American people.

Senator MCCAIN. Thank you.

Secretary Duncan, it may not be a large item in the scheme of things, but when you close schools, parents have to stay home with the children; some of those are health care providers. What is the answer?

Secretary DUNCAN. Well, the answer is we have worked extraordinarily hard to dramatically reduce the number of schools that are closed, and those numbers are down—as I mentioned in my testimony—very significantly from the peaks in the spring. So closing schools is an absolute last resort. We have seen great response so far this school year, and, again, those numbers are down almost 90 percent from their peak last spring. And so we are doing every-

thing we can to keep schools open. It puts a strain on families. I worry about children who do not eat—who rely on those school lunches—when schools are closed. That is very difficult to do. The social disruption of closing schools is huge, not to mention the loss of learning opportunity. So our guidance has been very clear that, whenever possible, keep schools open, keep sick children home, and let the majority of students attend school. That is critically important to us for a multitude of reasons.

Senator MCCAIN. Well, thank you. My time has expired. I have been observing you, Secretary Duncan, and your efforts at improving education in America, and I applaud many of your efforts, and also occasional displays of courage.

Secretary DUNCAN. Thank you, sir.

Senator MCCAIN. Frequent displays of courage. Thank you.

Chairman LIEBERMAN. Thanks very much, Senator McCain.

Do you have that on tape, Secretary Duncan? [Laughter.]

Secretary DUNCAN. I hope someone captured it.

Chairman LIEBERMAN. Well, you deserve that. I thank Senator McCain for saying that.

Senator Kirk, you are next.

#### OPENING STATEMENT OF SENATOR KIRK

Senator KIRK. Thank you, Mr. Chairman, and thank you to the Secretaries for your service, and through your prepared testimony and your oral testimony, the obvious collaboration that is going on is making a difference in terms of making an effective effort on this important issue.

This morning's *Boston Globe* had a lead story that basically points up the issues that have been discussed, and that is the shortage of the H1N1 vaccine and the overrun for the traditional seasonal flu vaccine. As a result of the lack of supply or delay in supply of the H1N1 vaccine, your partners at the State and local levels who have planned for their clinics have been advised to shut down the clinics until the supply takes place. So there has been some disruption in the supply chain and obviously some frustration at the local level.

I just wanted to understand. On the overrun of the vaccine for the seasonal flu, I assume that parents and others are saying, "If I cannot get the H1N1 flu vaccine, I should try to immunize my children by getting the seasonal flu vaccine." Is that a fair medical assumption? In other words, will the seasonal flu help to immunize at all from the H1N1 flu?

Secretary SEBELIUS. Unfortunately not, but we would strongly recommend and have recommended that particularly for vulnerable populations they get both. If this virus had been identified earlier than April when it was found, it would be mixed with the seasonal flu vaccine this year. It is just a different novel strain. But since it is a different novel strain and it is not mixed, there really is the requirement of two separate vaccinations.

Right now, Senator, just to give you the numbers, we typically have about 114 million Americans who get seasonal flu shots. Already here in mid-October, 82 million of those vaccination doses have been out to States and in some cases are running out, I think because people were hearing a lot of flu dialogue, so they are show-

ing up a lot earlier at flu clinics, and that is, frankly, good news, but they need to go back and get the H1N1.

Senator KIRK. And just as a follow-up on that, given the overrun, if you will, on the seasonal flu at this time, is there any danger that we will be in short supply of that as we move down the trail here?

Secretary SEBELIUS. No. Actually, we have been assured that production is, again, ramping up. We had an early run, if you will, much earlier than typical, on seasonal flu. So the production manufacturers are backfilling that, and, again, that will be widely available.

We may have a much higher take-up rate, though, than is usual. I was very alarmed when I saw the data that typically for seasonal flu, which kills 36,000 people a year and hospitalizes a couple hundred thousand people a year, our take-up rate is less than 50 percent for most categories, including health care workers. Fewer than 50 percent of health care workers ever get a seasonal flu shot. The only category of Americans who take great advantage of the seasonal flu vaccine are the older Americans, over 65.

But I think what we are going to see this year is a more robust response from every category, and, frankly, that is good news.

Senator KIRK. Thank you. The other question I had related to the colleges in Massachusetts, and, happily, we have a number of colleges and universities. And as I understand it, the allocation of the vaccine is determined by population per State. Is that correct?

Secretary SEBELIUS. Yes. As it becomes available, it is being pushed out on a per capita basis.

Senator KIRK. Right. Has there been any consideration given to the inclusion of out-of-State student population, of which we probably have as many as perhaps any other State? Is that configured or considered at all as you measure population and distribution of the vaccine?

Secretary SEBELIUS. Senator, I think it would determine how students are counted in Massachusetts and what your per capita count looks like. What is happening, though, is that those decisions about how much to order and where those orders are going are all being made at the State and local level. So I can assure you that whether it is Governor Patrick or your State health officials or others, they are very mindful of getting the vaccine to the spots needed and drawing down those orders and making sure that they show up on campuses and at schools.

Senator KIRK. Thank you, and perhaps Secretary Duncan can help on this.

Again, in terms of the delayed delivery of the H1N1 and the oncoming Thanksgiving holidays and so forth, if students, for instance, go home for the holiday and come back, and let us assume, sadly, one or more is afflicted with the H1N1 flu, are the colleges encouraged to use their facilities as clinics and health facilities?

Secretary DUNCAN. Absolutely, and many colleges are prepared to do that and are stepping up. They have health care clinics. This is a natural part of their outreach, so, yes, and I could check some of your colleges and universities specifically, but we absolutely are encouraging that, yes.

Senator KIRK. Thank you. The final area is one that has been brought up as well by the Chairman and the Ranking Member, and it is the question of why we are not helping ourselves and our neighbors across the globe in terms of production, manufacturing, licensing of these products? And I understand that we cannot really get the perfect vaccine until the flu is in the air somewhere and that takes some time and has some challenges. But I am troubled by the fact that we do have these glitches, that only one of five, as I understand it, producers is a United States producer. And maybe not for this morning, but I wonder if there are some things that Health and Human Services, Homeland Security, and the public health officials of the country could recommend, perhaps through this Committee or another, what we collectively should be thinking about to bring that talent and research and development skill and production skill back here—first, as a global partner; but, second, in terms of our homeland security should flu be inflicted for some deliberate reason, we want to be able to protect our citizens as well. And for the long term, I would think this would be an important investment and would encourage our departments to be thinking together about that and maybe suggesting to the Congress how we might be helpful as well.

Secretary SEBELIUS. Well, Senator, I think that is a very wise suggestion. Clearly, we are going to have a lot of lessons learned from dealing with this pandemic situation that will, I think, be enormously helpful.

What is the good news, I think, is that Congress, starting in 2005, began a multi-year investment in a variety of planning efforts, including our own research and development wing at HHS—BARDA—which exists as a laboratory to begin to look at potential issues. We do have five manufacturers at this point. That is up from two in 2004. HHS has been investing in helping build capacity around the world. It not only is important here in the United States, but we are now in a situation where also much of the world relies on our manufacturing capacity to, again, supply vaccines. So helping our nations around the world build capacity to take care of their own populations is part of that multi-year investment.

But I think you are absolutely right. We need to refocus on more internal manufacturing capacity and, again, new technology because we are still using vaccination technology of a number of decades ago, so we need to accelerate the cell-based technology that could more rapidly get from an identified virus to a vaccine.

Senator KIRK. Thank you all. Thank you, Mr. Chairman.

Chairman LIEBERMAN. Thanks, Senator Kirk.

If I could just add an exclamation point to the last question Senator Kirk raised, there have been news reports that in at least one case—I believe it was the Canadian producer of a vaccine that was under very understandable pressure from the Canadian Government to fill Canadian needs for the vaccine before they filled ours. It is exactly what we would do with an American producer. And it just puts up an exclamation point on the importance of developing domestic capacity for production of vaccine in these cases.

I am not blaming Canada, but I suppose in some sense you could say that—it is not the whole answer—the shortage of the vaccine today, beneath what we would want it to be, is attributable to for-

eign countries telling their local manufacturers, “Hey, you got to fill our needs before you fill anybody else’s.” Thank you.

Next is going to be Senator Burris.

#### OPENING STATEMENT OF SENATOR BURRIS

Senator BURRIS. Thank you, Mr. Chairman. The distinguished Secretaries have answered most of the questions, so I just have a couple of brief ones before I run off to the floor to make a speech, and I just hope that we could deal with this area. A couple of questions.

Now, we know that certain minority populations are considered high risk due to the prevalence of pre-existing conditions such as diabetes and asthma. We also know that minorities and low-income populations are less likely to get vaccination against the flu. How are your departments working to reach out and educate these groups about preventing measures and encouraging them to get vaccinated? And that goes for the schools, too, for Secretary Duncan, but first, Secretary Sebelius?

Secretary SEBELIUS. Well, Senator, I think you have raised a very important point, and we identified early on some of the challenges of getting to high-risk populations in a variety of ways. So, in addition to the normal sites, we asked very early on for our State and local partners to think carefully about sites that would be available to encourage hard-to-reach populations to get vaccinated, and that is going on. We are working closely with the faith-based outreach office for not only HHS’s office but the White House’s office to talk about how we reach into communities where people may not be presenting themselves traditionally for seasonal flu but to get the word out.

We have had an enormous effort outreaching to not only the African American press—radio, TV, print—but also the same thing in the Latino community and working with tribal leaders to try and make sure that information is available. So that combination we hope will not only get the word out but hope to encourage people that it is safe, it is secure—

Senator BURRIS. To go get vaccinated.

Secretary SEBELIUS. You bet.

Senator BURRIS. Yes, Secretary Duncan, on the educational side, you have those urban schools. How are we dealing with this?

Secretary DUNCAN. I think, again, what you have is folks who traditionally maybe did not trust—and this is why I think schools are so important. There is a level of trust. Every low-income minority child hopefully is in school. They have a relationship with the teacher. They have a relationship with the principal. So having schools as sites to be vaccination clinics I think is hugely important. They know the families, they know the community, and they can say, “Hey, this is important to do.” And, again, there always has to be parental consent. We are not going to mandate anything like this. But having schools step up in, whether it is an urban or rural area, in Illinois or around the country, I think is hugely important. So far I have been just extraordinarily impressed by school officials’ willingness to be part of the solution here.

Senator BURRIS. So you do not see any lag in any of the areas where you are making the emphasis?

Secretary DUNCAN. Well, we will see, and again, the question that Secretary Sebelius keeps raising is how many folks are actually going to step up to the plate. But having schools as sites, reaching out to the religious community, reaching out to faith-based leaders, we need to continue to work hard at this, but we do not know yet. And we have to do everything we can to make sure that not only is it available but people are taking advantage of what is available, and there is a difference between those two.

Senator BURRIS. Thank you.

Secretary Napolitano, you had mentioned the hospitals and all of these areas that you are setting up with the tents and making sure that you are having facilities available. I am just wondering how you are going to be dealing with medical staffing to cover these—should the overload of people show up in emergency rooms that they cannot handle, are there medical personnel capable of then being able to handle all this?

Secretary NAPOLITANO. Thank you, Senator. I was just giving some examples of what localities have built into their plans. It is not as if we are going to see tents all over the United States. But it is part and parcel of each locality, making decisions about how you triage patients, how you deal with those with milder cases of the flu who may present or even the worried well, without using the actual emergency room and really reserving that for those who need the most serious care.

With respect to health care providers, we have worked with—and, again, we start with local and State. They are the primary planners, as it were, of how to handle any type of epidemic within their own State boundaries. And then we have augmented that with identifying teams that can at a State or locality's request—Senator Collins mentioned an example—come in to provide assistance.

Senator BURRIS. Yes, but, Madam Secretary, it would raise a question to me whether they come into the emergency room or whether they come into a situation of overcrowding. Maybe the CDC can answer that question. I am concerned about the medical personnel being able to then handle the situation, whether you put a tent up or whether you have them lined up in the emergency room. If the doctors just came off their 48-hour shift in the emergency room and they had two or three cardiac situations, and now the people are coming in with the H1N1, is the staffing of the hospital going to be adequate to handle that onslaught? Is that being planned by the States or any other health care providers?

Secretary NAPOLITANO. That is part of the planning process that has been underway, and we are going to see that not just this fall but this spring as well. And there is no uniform answer across the country because the situation will vary where you are in the country, where hospitals are located in the country; urban, rural, that is a big issue across the country. But, again, that is why the focus has been on doing this kind of planning.

Senator BURRIS. Thank you.

Secretary SEBELIUS. Senator, I think also that part of the planning effort underway has been this multi-year strategy so hospitals deal not only with their bed capacity but with the provider capacity, where they can draw down additional personnel. We have,

among other things, a sort of medical reserve corps that came together after September 11, 2001, about 200,000 people identified—some of whom are medical personnel who are retired, others are volunteers—to help with the triage situation. We have about 6,500 commissioned corps members who are able in situations to be deployed if needed, so people who can move around to areas.

But, for instance, here in Washington, I visited one of the surge hospitals. There is a facility set up here in D.C.—and there are five of these around the country—designed specifically so that as local hospitals would reach capacity, you would actually have a unit that would come into high readiness who could figure out where to send patients, where to send personnel, who is ready and able to do just that. So the infrastructure, I think, for planning is there.

What you see right now in some of the tent situations—and there are hospitals with tents—they have wisely decided, rather than having a potentially very sick person sit in an emergency room and cough and sneeze on everyone around him or her, sharing the virus, to actually triage those folks in a more isolated situation outside. So some of what you are seeing is really the planning that the Secretary has talked about being implemented, how we separate people who really may need to be eventually in the hospital, but how to make sure that they do not make other people sick while they are waiting to be seen.

Senator BURRIS. You have satisfied my questions, and I am glad to hear that those plans are underway, and good luck to you. Let us do it. Thank you all very much. God bless you.

Secretary NAPOLITANO. Thank you, Senator.

Senator BURRIS. Thank you, Mr. Chairman.

Chairman LIEBERMAN. Thanks very much, Senator Burris. Senator Tester.

#### OPENING STATEMENT OF SENATOR TESTER

Senator TESTER. Thank you, Mr. Chairman, and I want to thank all three of you for your testimony and for being here today.

In a previous question, Secretary Napolitano—and this is a question for you, Secretary Sebelius—had said that additional screening is not being done at the border, and I tend to agree with that. So just for my information, is the outbreak of H1N1 greater or about the same in Canada, Mexico, China, India, and Europe?

Secretary SEBELIUS. Well, again, we are monitoring that regularly. We are seeing about the same presentation as this travels around the world. The good news was at least in the Southern Hemisphere, which went through their flu season without vaccine, is we did not see a mutation.

Senator TESTER. OK. So we are—

Secretary SEBELIUS. But it is spreading, the same target populations, the same—

Senator TESTER. The same target population, about the same occurrence for population.

Secretary SEBELIUS. Right.

Senator TESTER. For example, is Canada or Mexico doing the same thing we are?

Secretary SEBELIUS. Yes, there is a very coordinated effort not only in the Americas, if you will, who we are out in front of this,

but throughout the world in terms of vaccination, mitigation, and sharing information, sharing strains, surveillance teams. The reason it is a pandemic is it is global.

Senator TESTER. And to get to the point that Senator Kirk had raised and that the Chairman had followed up on, should the United States be more entitled to that vaccine than some other country in the world?

Secretary SEBELIUS. Well, I think the balance is difficult. The President clearly has made it clear that his priority is safety and security of the American people, and immediately he also adds that we are a global partner. So we have joined now with 11 nations in terms of 10 percent of the vaccine will be made available to developing countries. We stepped up and organized.

Senator TESTER. I mean, I agree with that. But since there are four suppliers outside this country and one inside this country, why wouldn't they supply, for instance, to the highest bidder or to their own people first?

Secretary SEBELIUS. Well, it is the orders, and one of the things that we urged Congress to do—and, wisely, you did it—is that in the supplemental appropriation bill, you granted resources so we could place orders on behalf of the United States, and it really is—the orders will be filled in priority terms.

So we are really sort of at the front of the line with some of these in terms of getting vaccine as it is produced.

Senator TESTER. I appreciate that. I guess the whole concern of outsourcing everything and now we are here outsourcing this, and I know you have the same concerns.

You talked about cell-based versus egg-based research that is being done. I was wondering. Is that research being done in this country?

Secretary SEBELIUS. Yes, not only is BARDA engaged in that, but a lot of work being done at the National Institutes of Health (NIH) right now. But I would say it is going on all over the world, too. Really at this point, everybody is trying to get a much faster growing technique.

Senator TESTER. You talked about the robust response to the vaccination. At this point in time, can you tell me if you get the vaccination, is it 100 percent you will not get the flu?

Secretary SEBELIUS. I do not think anything is 100 percent, but we are seeing an 85-, 90-percent response, which is very good.

Senator TESTER. And how about if you have had the flu, the H1N1, can you get it again?

Secretary SEBELIUS. We do not know, but the scientists are saying get the vaccine.

Senator TESTER. Rural versus urban, have you seen any difference in outbreaks there?

Secretary SEBELIUS. Not that we know of. I am asking my CDC sources. I thought that was the answer, but I want to give you correct information.

Senator TESTER. This is for you, Secretary Duncan, and you touched on it a little bit in your opening remarks. That is, there are a lot of folks that get school lunch programs, school breakfast programs. They get sick, they head home. Are there any concerns as to whether they are going to get the proper nutrition at home?

And this is really wild for me. It shows where we are at, I guess. It is just crazy. But is there any concern about nutrition at home versus what they would get in the school? And what can be done about that?

Secretary DUNCAN. Absolutely. That is a very real concern. I think there are multiple reasons, that being one of the main ones, why it is so important to keep schools open and do that whenever possible. Just to put it in context, at its peak last year one day we had 980 schools closed. As of yesterday, we only had 88 around the country—so a 90-percent reduction. That is 88 out of 95,000 schools in the country. So we are trying to keep schools open so that kids can eat.

Senator TESTER. But for those kids that go home, I mean, that is beyond your purview, correct?

Secretary DUNCAN. No. We are actually working on it. It is beyond my direct purview, but we are working very closely with Secretary of Agriculture Tom Vilsack and his team and really thinking about, if these closures are for a protracted period of time, how we do some—

Senator TESTER. I appreciate that.

Secretary DUNCAN [continuing]. Feeding at the school, and so the Department of Agriculture (USDA) has been really thoughtful on this and is part of the partnership.

Senator TESTER. I appreciate that. School nurses, are they still a part of the equation, or did they go by the wayside?

Secretary DUNCAN. No. They are leading this thing. They have been phenomenal.

Senator TESTER. OK.

Secretary DUNCAN. We would not be in this position without their extraordinary leadership.

Senator TESTER. Is their availability in rural America the same as it is in urban America?

Secretary DUNCAN. I think there is a scarcity of nurses everywhere. I do not know if it is a rural versus urban issue. We do not have enough school nurses.

Senator TESTER. Any idea on what the staffing of school nurses are in our public education system today? Are we understaffed by 20, 30, 40, or is it near 100 percent?

Secretary DUNCAN. I think education is underfunded, and one of many places where education is underfunded in school nurses. So, yes, I would say we are underresourced in nurses—urban, rural, and suburban.

Senator TESTER. Could you find out what that is? I would really like to know what that is. I do not expect you to know it, but I would love to find that out. And if there is a difference between urban and rural, I would like to know that.

Secretary DUNCAN. I will check that.<sup>1</sup> I will tell you they are working unbelievably hard, the ones we have, and I could not be more proud of them.

Senator TESTER. Yes, but I think it is one of the keys to maybe getting our arms around this.

<sup>1</sup> Secretary Duncan's response to Senator Tester's question appears in the Appendix on page 334.

Secretary DUNCAN. Yes.

Senator TESTER. Secretary Napolitano, I did not want to leave you out of this. We are bringing in vaccines from other countries, produced in other countries. Is there anything that you have done to expedite their ability to get across the border? Or can it be done as per usual?

Secretary NAPOLITANO. There has been no reported delays at that particular issue, Senator, and there will not be.

Senator TESTER. Good. I want to thank you all very much for your testimony and your concise answers. Thank you very much.

Chairman LIEBERMAN. Thanks, Senator Tester.

Senator Carper, with your permission—you got here a little earlier, but Senator McCaskill has been here all morning, so I am going to call on her first.

Senator CARPER. You are kidding. [Laughter.]

I just want you to show me—no, go ahead.

Senator MCCASKILL. There you go.

Chairman LIEBERMAN. Yes, Missouri. Senator McCaskill, then we will go to Senator Carper.

#### OPENING STATEMENT OF SENATOR MCCASKILL

Senator MCCASKILL. Thank you.

I want to make sure I understand. You know, we have a problem with reporting both ways, I think. We want to make sure that the information we are getting is accurate, but there is also, I think, right now because of the heightened awareness, some inflationary reporting that may be going on. I want to make sure I understand this document.

This says the percentage of all visits to doctors' offices that are due to flu symptoms, is my understanding.

Secretary SEBELIUS. Flu-like symptoms.

Senator MCCASKILL. Flu-like symptoms. So, indeed, this spike is not confirmed cases of H1N1. It is, rather, the tendency of the population right now to go to the doctor more quickly when they have flu-like symptoms because of all the attention that we justifiably have put on this new flu virus. Correct?

Secretary SEBELIUS. That is correct, Senator. We are actually not testing individual cases any longer. We are testing cases of hospitalizations and deaths to make sure that we are tracking really whether the virus has mutated. But the treatment for the flu is the flu is the flu, so we are not testing at that point. So these are not confirmed H1N1 cases.

Senator MCCASKILL. So in some ways, this chart is good news because it means people are more likely to go to the doctor right now because of flu-like symptoms than they were this time last year. Would that be a fair statement?

Secretary SEBELIUS. I think that is a very fair statement. I have been told by Dr. Schuchat, we have virological surveillance, and that is also showing an uptick, and we use multiple systems to get the tracking. But you are right, this may indicate that people are concerned. We have seen definitely an uptick in seasonal flu vaccine uptake, which is good news.

Senator MCCASKILL. Right, which is good news.

Secretary SEBELIUS. Getting that public health information out, we have a vaccine, go get vaccinated. In the past, people did not pay a lot of attention to it except older Americans, and now a lot of people are paying attention, and that is good news.

Senator MCCASKILL. So that we can have some perspective of what the numbers are that we can confirm, what are the confirmed deaths to H1N1 this year compared to what the typical deaths of regular flu would be in a year?

Secretary SEBELIUS. I want to get you the accurate—I know we have 86 confirmed H1N1 pediatric deaths, and that is as high, if you average the last several flu seasons, as we have in the entire regular flu season. So that is a high number because typically—

Senator MCCASKILL. Obviously, because of the kids.

Secretary SEBELIUS [continuing]. The kids do not die with seasonal flu.

Senator MCCASKILL. Right. But the overall numbers, what are they, regardless of pediatric or otherwise?

Secretary SEBELIUS. What I have been told by Dr. Schuchat is that is really the number that is probably the best number to track, that and the hospitalizations. What we know now is 90 percent of the hospitalizations are the under-25-year-old, which is a very different number than we see in seasonal flu. So those trends are really what we are looking—36,000 people every year die from the seasonal flu. About 200,000 are hospitalized. So we are significantly below those numbers, but this is a very different population, and it is moving.

Senator MCCASKILL. Well, and I understand the point you are making is that we need to pay attention because we have a different population that appears to be vulnerable to this flu, and obviously it is a population—

Secretary SEBELIUS. And flu is serious, year in and year out.

Senator MCCASKILL. Absolutely. But I still want us to get perspective, that the number of deaths per year from the flu that we are all familiar with wildly exceeds any confirmed death number for H1N1 at this juncture.

Secretary SEBELIUS. That is absolutely correct.

Senator MCCASKILL. Speaking of statistics, it is my understanding now you guys have quit trying to collect individually and now you are just doing regionally. Is that correct?

Secretary SEBELIUS. We are not—

Senator MCCASKILL. Hospitalizations?

Secretary SEBELIUS. Oh, hospitalizations, we are getting reporting, yes, out of State, yes.

Senator MCCASKILL. Let me talk about fraud for a minute. Because of this heightened awareness, the good news is we have a lot more people going to the doctor because of the heightened awareness. We have more people getting the regular flu vaccination because of the heightened awareness. I think everyone is paying attention, which is terrific. But there are also hoaxes out there right now.

Secretary SEBELIUS. You bet.

Senator MCCASKILL. There are people advertising fake drugs, going on the Internet and saying, "Click here, and we can save you from H1N1." Can someone address for me the fraud issue and what

you all are doing to protect consumers in this country from scumbag con men and women?

Secretary NAPOLITANO. Well, with respect to our scumbag initiative— [Laughter.]

No, we are addressing that and have been through Immigration and Customs Enforcement (ICE) and Customs and Border Protection (CBP), going after counterfeit narcotics. We have undercover investigations on the way. We are looking both at undercover physical sales, mail sales, Internet sales, and the rest. Field offices have all been given guidance in terms of these kinds of investigations. We are also coordinating inspections at the border. And it is my understanding that the State attorneys general are also going after the fraud element.

There is a fraud element that seems to accompany any kind of—

Senator MCCASKILL. Any problem we have got, somebody is going to take advantage—

Secretary NAPOLITANO. Yes, there is going to be a fraud element.

Senator MCCASKILL. Right.

Secretary NAPOLITANO. And so part and parcel of what we have been implementing and planning for now is dealing with that fraud element.

Secretary SEBELIUS. Senator, also, I would say the Food and Drug Administration is being very aggressive in terms of—actually the Deputy Director recently ordered a series of products to determine indeed that they were scurrilous and fraudulent, and they are clamping down in terms of medical claims being made, making it very clear that people need to be very cautious about purchases. But, unfortunately, there are folks selling things out there to take as medication or flu prevention that are totally bogus, and so we are not only going after it in the legal realm, but also in the medical realm.

Senator MCCASKILL. Well, I think with the heightened awareness out there right now and the media interest in this, the sooner you guys can put somebody in handcuffs on TV for doing this kind of thing, the better off we are all going to be, because it would get a great deal of attention right now, and that would have the kind of deterrent effect, as you all know—I know certainly Secretary Napolitano knows—there are certain crimes you can deter and there are certain ones you cannot. This is one you can deter with some high-profile prosecutions, and I would certainly urge you in your collaborative fashion—which is great the way you are working—to get with the Attorney General and to get with Justice and to get with the National Attorneys General Association and even the National Prosecuting Attorneys Association, and see if you guys cannot ramp up some significant prosecutions as quickly as possible so we can save some heartache for a lot of people that are going to be taken advantage of.

Finally, let me just ask one definitive question. There are thousands of hard-working Missourians that make their living raising hogs in Missouri, and this is a difficult time for them in this economy. Can we state for the record definitively—it cannot be said often enough—that no one can contract H1N1 from eating pork?

Secretary SEBELIUS. No one can contract H1N1 from eating pork.

Senator McCASKILL. Did you hear that, Mr. Chairman?

Secretary SEBELIUS. No one.

Senator McCASKILL. No one can contract H1N1 from eating pork.

Chairman LIEBERMAN. Yes.

Secretary SEBELIUS. In fact, it may protect you. I am not exactly sure, but it may.

Senator McCASKILL. Pork is delicious. You can go bacon if you are not on a diet. You can go lean, the other white meat, if you are on a diet. Pork rules. There is no reason to avoid pork. Thank you, Mr. Chairman. [Laughter.]

Chairman LIEBERMAN. Unless, of course—

Secretary NAPOLITANO. Yes, let us be specific about the kind of pork we are talking about, right? [Laughter.]

Senator McCASKILL. Unless it is an earmark.

Chairman LIEBERMAN. No. Unless, of course, you respond to a higher authority. [Laughter.]

Senator McCASKILL. Sorry about that, Mr. Chairman.

Secretary SEBELIUS. You will not get H1N1.

Chairman LIEBERMAN. It has nothing to do with H1N1. Thanks, Senator McCaskill.

Senator Carper, thank you for your patience.

#### **OPENING STATEMENT OF SENATOR CARPER**

Senator CARPER. For those of you responding to a higher authority and for those of you just somewhat leery of eating pork, as a guy who comes from a State where there are 300 chickens for every person, there are other alternatives. [Laughter.]

I would just lay that at your feet.

Before Senator McCaskill leaves, I just want to say how much I enjoyed listening to her questioning. We serve on a couple different committees together, and I love especially the new words that I learn from her. One of my favorites is “pond scum.” That is a word we are starting to spread around Delaware as well, not the pond scum but certainly the terminology.

My colleague from Montana has left, but he raised the issue of school nurses and whether they have too few school nurses and so forth. In one State—and that is my State—every public school has a school nurse. In my State, every high school has a wellness center. And we are very proud of that, and we decided to do that about a dozen or so years ago. We are not the only State, I am sure, who has done that, but we feel that it has positioned us for challenges just like the one that you all are helping us to address.

I want to say, too, to the Chairman, I do not think you could have three better witnesses here today. This is the A Team, and we are delighted not just for the work that you are doing and your Departments are doing, I love the way you are collaborating. And I remember we used to battle in my old job, there were a whole bunch of challenges in our State, traditionally the departments worked in stovepipes and there was not the kind of collaboration. We worked on it for 8 years to try to change that, and I think with some good effect. I am sure that Governor Napolitano and Governor Sebelius are fully familiar with that in your own States. But I love the way that the three of you are collaborating, and it is not just the three of you, but the folks who work for you as well.

I want to say, Mr. Chairman, I think this idea of taking the right approaches, being careful ourselves in things that we do, the way we cough and wash our hands and so forth. I think it is starting to spread. I was walking down the hall for the second time coming back to this hearing. As I walked down the hall, I walked by a lady standing at the elevator, and I watched her as I walked along. She removed from her purse a tissue, and she use that tissue over her finger then to hit the down button, and I have never seen that in my life. [Laughter.]

I think the message is getting out there.

We have had a couple of personal brushes with H1N1 in our own family. Our oldest son, who goes to school up in the Boston area, is a senior up there, and he is a pretty good athlete, too. And he was stricken about 3½ weeks ago, with H1N1. Did not miss any classes but was sick every day for about 3 or 4 days. And just to show you how quickly you can bounce back from this stuff, he ran a marathon on Sunday. So I would not suggest that people get H1N1 just so they can prepare for marathons, but they do bounce back.

I mentor on Mondays at a K-5 public charter school in Wilmington, and last week they closed that school on Wednesday and closed it for the balance of the week and reopened it on Monday. I was there Monday, and we had just about everybody back. So kids are resilient. They do bounce back.

I want to, if I could, mention two things, and a question first of all, if I could, for Secretary Napolitano and Secretary Sebelius. In addition to the terrific men and women who comprise our first responders and hold the lines every day in protecting the public from the spread of serious illness, we also have in our back pocket an immense technological arsenal to help our government to fight diseases and influenza from taking over our communities. And whether it is the various surveillance models, modeling programs that help us predict where to apply countermeasures next or advanced vaccines such as through vapor mechanisms, I feel that we must continue to invest in these kinds of technologies, and I would urge you to continue to do that.

If possible, would either or both of you please take a moment to describe your respective departments' approaches to incorporating or seeking out new technologies to fight current and future pandemic outbreaks?

Secretary NAPOLITANO. I will start, Senator. We have an entire Directorate that is called "Science and Technology." I would mention that we are still waiting for the Under Secretary to be confirmed there. Her name has been pending for quite a while. But that department is where we focus a lot of our research and outreach efforts, and, one of the goals that we have is to be actually more robust in some of the research that we are doing, not just in terms of pandemic, but other issues that can affect the public safety of the populace.

Senator CARPER. All right. Thank you. Secretary Sebelius.

Secretary SEBELIUS. Senator, we have, I would say, multiple agencies within the Department who are, again, collaborating on this. We have the science team led by NIH, which has the vaccine program; the Food and Drug Administration, who has the regu-

latory and safety steps authority; and the Centers for Disease Control and Prevention, which has surveillance and outreach capabilities. And they work very closely on things related to vaccination.

We have an assistant secretary who is specifically focused on emergency response. As you know it is not only the pandemic effort, but what happens after a different kind of disaster, a regional disaster, how that medical response is done, everything from search and rescue to ongoing meeting the medical needs. So we have a focused unit on that.

We have a very robust Global Health Affairs Office that is, again, trying to coordinate some of this activity internationally, and we work closely with the World Health Organization in terms of responsiveness efforts.

I have an Assistant Secretary on Health. I would say that within our agency we have virtually every department kind of teed up on this. Our Office of Children and Families is looking at everything from Medicaid waivers to try and get populations out and reimbursed to what we do with kids in foster care. We had a meeting last week on homeless shelters, a real challenge in terms of isolating sick people. If you have families in a shelter, where is an ancillary isolate? So working with the Department of Housing and Urban Development (HUD) on trying to figure this out.

So we have had a sort of “all hands on deck” moment within the Department, which I would say has been a very good effort not only within the Department but certainly with colleagues across the Cabinet.

Senator CARPER. That is great. One of the things I am very proud of that is going on in my State—and my guess is it is going on in your States and other States as well—is trying to find new ways to develop vaccines using things like tobacco plants in order to derive them, and trying to move away from an egg-based vaccine that sometimes takes a long time to create and a long time to replicate.

As this outbreak continues to grow, and with the vaccination programs that are being rolled out in all of our communities across the country, we have been seeing an immense amount of misinformation surrounding not only the vaccinations but also the Federal Government’s policy on who is to receive it as part of their profession. Specifically, I am referring to the false reporting of how the Federal Government is employing a mandatory vaccination program, which, as we know, is not true. And this may have been discussed when I was out of the room, but let me just ask you to take a moment and just briefly describe the work that you all are doing to dispel these false rumors, and maybe give us some advice as to how we can help.

Secretary SEBELIUS. Well, Senator, it is a great point. What we are trying to do, among other things, is encourage people to visit flu.gov, the one-stop shop. We have a whole series of myths and facts: Is the vaccine safe? What are you finding out in clinical trials? What has happened to try and dispel some of the rumors that are, unfortunately, making people have second thoughts about vaccinating their children or getting the vaccination themselves.

In terms of the mandatory versus voluntary, I think the confusion has been that there are some local health systems who have

decided that their employees must be vaccinated in order to come to work, and I would suggest this did not start with H1N1 vaccine. There are some local health units that decided that a number of years ago with seasonal flu vaccines. They did not want their workers either to be sick with the seasonal flu or potentially make patients more sick than they already were in the hospital. But that has led to, I think, misinformation.

The Department from the outset has recommended a voluntary vaccination program. We continue to recommend that. That does not override the local authorities' opportunity to impose some mandatory guidelines, but that has not come from our Departments, been advised by our Department, or been advised by the CDC. So we are just continuing to try and get the message out.

You are a great messenger in Delaware, so I hope you are helping us spread the word about what is real and what is not, but urging folks to visit flu.gov I think is a very good way to get parents, employers, and providers some real information.

Senator CARPER. Great. Thank you. Flu.gov it is. I want to say, Secretary Sebelius, we were so grateful to you in Delaware for coming to our State earlier this year. We look forward to welcoming Secretary Duncan to the First State next Tuesday morning with Race to the Top. Race to the Top with Arne Duncan. Thanks so much.

Chairman LIEBERMAN. Thanks, Senator Carper.

I want to thank the three of you for your testimony this morning and go back to the beginning and thank you for the work that you have done since this H1N1 virus appeared and broke out in April of this year. Obviously, you are hearing from the Committee some of what you are feeling, which is the impatience, the restlessness, and frankly just plain anxiety about the H1N1 flu spreading. Senator McCaskill was right. The chart does reflect the percentage of all doctor visits that are due to the flu, but I think that parallels the increase in not just anxiety but the actual incidence of the flu. So this is a real problem.

And on the three points that I raised at the beginning, I come away understanding better why we are going to be about 25 percent short of the vaccine at the end of October that the manufacturer said that we would have. But I know that you understand it, and I know you will do everything you can to push them to get this to us as quickly as possible.

I appreciate what you have done to expedite the distribution system, too. That is very important. But the reality is that there is not enough now, and we have got to get ahead of the spread of the disease.

On the second point, on the hospital preparedness, on how the public health system is prepared for the potential surge that is beyond its capacity, I am encouraged from what you have said to conclude that there is a lot of emergency planning being done in which the hospitals will have essentially off-site—if I am hearing you right—locations for the less severe cases, if that happens, and then use in-hospital facilities for the most severe.

I am also encouraged about the intravenous antivirals from your testimony, Secretary Sebelius, that a decision for emergency usage authorization will happen soon. My appeal to you after that hap-

pens is to the extent that you can, really the hope that you can, I want to say “over-order.” I do not think any of us want to be in a situation where there are people in critical condition in an ICU, their doctor and their family wants an IV antiviral, and we do not have enough of it. So based on—again, I hope the PCAST projections of 150,000 to 300,000 people in the country needing ICU care because of H1N1 infections, do not ever materialize. But God forbid they do, there are going to be a lot of people looking for the IV antivirals.

So, bottom line, thanks for everything you are doing. I know you are working really hard at this, and overall I am very grateful for what you have done. Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman. I want to thank you for holding this hearing and the three Cabinet Secretaries for appearing before us today.

I am heartened by the coordinated response. There is one issue that I had hoped to bring up that I will bring up for a response to the record, and that is, our investigation into the failed response to Hurricane Katrina showed a large variation among the States in their capabilities and their response when there is a crisis, whether it is man-made or naturally occurring. And for the record, I would ask that our witnesses today evaluate the evenness of the response across the United States and answer the question of whether you are targeting specific States that may not do as good a job as Maine or Connecticut is doing right now to ensure that just because some of our citizens live in states that have less developed capabilities they are not left behind as we fight this pandemic.

So that is an issue that we did not get to today, but that I would appreciate your responding to for the record. Thank you.

#### INFORMATION SUBMITTED FOR THE RECORD FROM SECRETARY SEBELIUS

It is important that States and local jurisdictions have the capability to appropriately respond during a crisis. Our Nation’s investment in public health infrastructure, particularly at the State and local levels, remains a critical challenge that has real life consequences. Our experience with the 2009 H1N1 pandemic, and the lessons we have learned, demonstrate a need to examine new paradigms for leveraging the public health infrastructure and our healthcare system to develop the needed capabilities to ensure every community is prepared to respond to and recover from future disasters.

As I mentioned earlier during my testimony, HHS is using multiple systems to track the impact of the 2009 H1N1 influenza outbreak on our health care system. We are in constant communication with State health officials and hospital administrators to monitor stress on the health care system and to prepare for the possibility that Federal medical assets will be necessary to supplement State and local surge capabilities. To date, State and local officials and health care facilities have been able to accommodate the increased patient loads due to 2009 H1N1 influenza, but HHS is monitoring this closely and is prepared to respond quickly if the situation warrants.

Since its inception in 2002, HHS has provided nearly \$7 billion to States through our Public Health Emergency Preparedness Program to help them develop and maintain critical public health, communications, and laboratory capabilities at the State and local level that are needed to prepare for and respond to emergencies. To supplement traditional PHEP funding, in 2009 Congress appropriated funding to prepare for and respond to the influenza pandemic. This funding became the Public Health Emergency Response (PHER) grant program. Through its four phases, over \$1.4 billion was provided to States to support activities including vaccination, antiviral distribution, community mitigation, laboratory, epidemiology, and surveil-

lance activities. In addition, since its inception in 2002, our Hospital Preparedness Program (HPP) has provided more than \$3 billion to fund the development of medical surge capacity and capability at the State and local level. A result of Congress' investment in these programs is that State and local health departments have developed plans for distributing and dispensing critical medications, have better mechanisms in place for disease surveillance efforts, and have initiated or improved coordination of their emergency response assets. Hospitals can now communicate with other responders through interoperable communication systems; track bed and resource availability using electronic systems; protect their healthcare workers with proper equipment; train their healthcare workers on how to handle medical crises and surges; develop fatality management, hospital evacuation, and alternate care plans; and coordinate regional training exercises.

As we learn from the experiences of the 2009 H1N1 pandemic, we look forward to working with you to improve strategies to ensure that our Nation has the right assets at the right time to minimize the health impacts of an influenza pandemic, hurricane, bioterrorism event, or other national emergency

Chairman LIEBERMAN. Thanks for raising that point. I agree totally. Do any of you want to say something in conclusion?

Secretary NAPOLITANO. No. I would simply say that an enormous planning effort is underway. The frustration now is with delay—not shortage but delay, although in context, this is a new flu that we did not even know about a few months ago. But the vaccine will be pushed out to over 150,000 locations as quickly as humanly possible, and in the meantime, we have a web of other plans underway so that business as usual proceeds in the United States and that we take care of our critical operations and critical information as we work through the problem.

Chairman LIEBERMAN. Thanks.

Secretary SEBELIUS. Mr. Chairman, I would just say that from the outset, Dr. Tom Frieden, the new head of CDC, reminded us that we will either have more than enough vaccine or a shortage of vaccine. There may never be the right amount.

The good news is, I think, people are educated and are eager for this immunization, and we will do our best to continue to ramp up the production and push it out the door and hopefully to work with our partners to mitigate the spread in the meantime.

Chairman LIEBERMAN. You know, it is a good point. I saw a couple of a stories that indicated it. In California, there were some people in the priority categories—I forget which was which, but in one State—this was California or New York. In one State, people in the priority categories were complaining that they did not have enough vaccine. In another State, they had it and some of them refused to take it. So that is the place we are in.

Secretary Duncan. Thank you for your leadership.

Chairman LIEBERMAN. Thank you all very much. We are going to leave the record open until Friday at the close of business for additional statements and questions, and because this is ongoing, to the extent that you can answer the questions as quickly as possible, we would appreciate it.

Secretary SEBELIUS. Sure.

Chairman LIEBERMAN. Thank you very much. The hearing is adjourned.

[Whereupon, at 11:52 a.m., the Committee was adjourned.]

## **H1N1 FLU: GETTING THE VACCINE TO WHERE IT IS MOST NEEDED**

**TUESDAY, NOVEMBER 17, 2009**

U.S. SENATE,  
COMMITTEE ON HOMELAND SECURITY AND  
GOVERNMENTAL AFFAIRS,  
*Washington, DC.*

The Committee met, pursuant to notice, at 2:57 p.m., in room SD-342, Dirksen Senate Office Building, Hon. Joseph I. Lieberman, Chairman of the Committee, presiding.

Present: Senators Lieberman, Carper, Pryor, McCaskill, Kirk, and Collins.

### **OPENING STATEMENT OF CHAIRMAN LIEBERMAN**

Chairman LIEBERMAN. Good afternoon. Thanks for your patience. As you know, we had two roll call votes on the Senate floor which intervened with our getting here on time, but I appreciate your being here.

We hold this hearing on the H1N1 flu outbreak against the backdrop of two crucial numbers going the wrong way: More flu deaths than previously realized and fewer vaccine doses than originally promised. And this has led to understandable public frustration and anger, mixed with confusion over just who should get vaccinated, with States and even individual cities and counties creating different priority lists.

It also has led, I am afraid, to some of the highest-risk individuals, such as pregnant women and children with asthma, waiting in those long lines for vaccine shots that ultimately were not available. And it has created anxiety, sometimes fear among parents going on wild goose chases trying to get vaccine for their children that their government says they need but that they, the parents, cannot find.

As I said in our previous hearings, I am very grateful for the work that Administration officials from the three agencies that are represented before us today have done since the H1N1 virus appeared in April. Particularly, the H1N1 vaccine was developed in record time and safely. And I know how hard each of you and the people you work with have been working since the onset of this global pandemic.

But with so many eligible Americans still unable to get the vaccine, I am afraid that a good situation has turned bad. I worry that we are undermining confidence generally in our public health system, and, of course, as I mentioned before, that some of the people most at risk from the H1N1 virus not only are having a hard time

getting vaccinated—some of them—but they may actually stop trying.

Last week, to get to the numbers, the Centers for Disease Control and Prevention (CDC) released new estimates of the toll the H1N1 virus has taken to date, and they are significant: 22 million Americans have become ill with this virus; 98,000 people have needed hospitalization; and approximately, a little short of 4,000 people, including about 540 children, have passed away, either directly from H1N1 flu or from a combination of the flu and complications from it.

That is a quadrupling of the previously reported death toll as it was understood in October, and I know a different count, a different system was used, which I think is actually a more accurate system, and I appreciate it and I look forward to Dr. Schuchat's testimony on it.

Another set of estimates, which is the amount of vaccine available, has unfortunately been revised downward again and again since planning for the pandemic began in April, and this I believe is really at the heart of what has caused so much frustration and fear, which I think was unnecessary. And, again, I want to explore this with the witnesses.

Three months ago, CDC estimated the Nation would have 120 to 160 million doses on hand by the end of October. That, as we heard in our previous hearing, was based on estimates that the manufacturers of the vaccine had made. Those doses would be used, first, to inoculate five target groups based on vulnerability: Pregnant women, caregivers of infants under 6 months, health care providers, anyone between the ages of 6 months and 24 years, and high-risk adults under the age of 65.

These groups total a very large number, actually more than half of the U.S. population, about 160 million people. And the consistent message to the public coming from the Department of Health and Human Services (HHS) and CDC was that these initial target groups needed to get vaccinated. So where did those numbers come from?

Well, we learn a lot as we go on. The Advisory Committee on Immunization Practices, a longstanding committee, is the one that identified those priority groups, but I was interested to learn that they also generated a secondary and smaller list of approximately 42 million people who were the most at risk—not just at risk but the most at risk—in case vaccine availability fell short of what was planned for. Those most-at-risk groups included pregnant women, again, caregivers of infants under 6 months, health care workers, but then a smaller subset: Children aged 6 months to 4 years and high-risk children aged 5 to 18.

Dr. Schuchat described this target alternative at a press briefing that CDC gave at the end of July as a “just-in-case scenario” that likely would not be needed, but which we should have in our—I think you said “back pocket.” And that made sense. Then 2 months ago, the just-in-case scenario became the reality we are dealing with today as the estimate of available vaccine dropped to 85 million doses, then by the end of October to under 27 million doses. Now there are here past the middle of November approximately 42 million doses available—remarkably and I guess coincidentally the

exact same number as the small most-at-risk target group by the Advisory Committee.

So the States were handed two sets of guidelines and told to use their own discretion with respect to how to implement them, either the broader group of those who are vulnerable more than most, which is 160 million, or the smaller group of those who are most at risk, 42 million. Some States opened their vaccination programs to everyone in the initial large target groups; other States, including Connecticut, took a more conservative approach and have started with the smaller targeted subset. But the general notification to people, including a lot of media focus on this, I think created tremendous interest and, in fact, anxiety about getting the vaccine.

The chart up there based on CDC data shows how significant the gap between what would be needed to provide enough vaccine for the 160 million people in the broad priority groups and the 42 million people in the targeted subset and what is actually available.<sup>1</sup> And I think—and I want to really invite the witnesses to respond to this—that is what has caused the public outrage, basically the initial description of the 160 million people who are eligible—not just eligible but at risk, and then ending up with now finally 42 million, which happens to be the number in the smaller subset.

At our hearing last month, Health and Human Services Secretary Kathleen Sebelius expressed optimism that the problems with manufacturing and production of the vaccine that had been the obvious cause for the much smaller number than had been predicted had been resolved. Things looked better 2 weeks ago when 11 million more doses were delivered, with another 8 million projected to be available last week. But by last Friday only about 5 million were available, and I am concerned, I want to ask the witnesses, whether this was a problem of forecasting or whether something again has happened at the manufacturing facilities.

Senator Collins and I wrote a letter to Secretary Sebelius after our last hearing raising many of these concerns, and I must say, respectfully, I did not find the Secretary's response to our letter satisfactory. She did explain in some detail why HHS made some of the decisions it made along the way, but the response to me just did not say that we have learned from this disappointing experience and we have learned how to make it better next time.

Look, bottom line what I continue to be concerned about is that after it became clear that the manufacturers were not going to deliver the number of vaccine doses that we expected, HHS did not say to everybody in the country, "Wait a second, we do not have as many as we thought. Now these are the ones who are most at risk, and, therefore, you should come in and everybody else should wait." Obviously, people who got there first got the doses, so some people who were not in that most-at-risk population got vaccinated, and others—pregnant women, children with asthma, etc.—who are most at risk did not get the vaccine.

So, mistakes are made. Things like this do not just happen, and I think it is important that we acknowledge them so that we can have confidence that we have adjusted our thinking going forward

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<sup>1</sup>The chart submitted for the Record by Senator Lieberman appears in the Appendix on page 347.

as this pandemic continues, and then that we have learned from this in a way that will make us better prepared for the next public health crisis of this kind.

Senator Collins.

#### OPENING STATEMENT OF SENATOR COLLINS

Senator COLLINS. Thank you, Mr. Chairman.

Mr. Chairman, thank you for holding this important hearing to focus on the continuing problems regarding the supply and distribution of the H1N1 flu vaccine.

This hearing is critical to peeling away the layers of misinformation and miscommunication that have hampered the Federal Government's flu response strategy.

Many of our constituents, especially those most vulnerable to the virus, are frustrated and perplexed by the problems they face in getting vaccinated. To illustrate that frustration, let me tell you the story of an 11-year-old boy named Brendon Stearns from Greenwood, Maine.

On October 27, Brendon wrote me a letter. He described his attempts to get the vaccine. He has two autoimmune diseases and asthma, placing him in the high-risk group for complications. Yet even after his mother called several possible sources—schools, the Maine CDC, doctors' offices both in Maine and in Boston, hospitals, health care clinics, and pharmacies—she could not find any vaccine available for her son. Finally, her persistence paid off when a source was found at a home health agency in Rockland. That was a nearly 6-hour round trip from this family's home in Greenwood.

I was dismayed to learn about the extraordinary effort this family had to undertake in order to get the vaccine for their high-risk child.

Brendon's mother also wrote me a letter in addition to his. She talked about the worry that her son went through. She said, "Brendon has already asked me what hospital he would have to go to if he contracts the virus." What a difficult discussion to have with your son. To have this thought running through an 11-year-old's mind is just not right. And that is indeed why we are here today.

Such extreme measures should not be required. And it raises troubling questions: How many others, just like Brendon, are still waiting for their vaccination?

Despite consistent reassurances from the Federal Government that the vaccine would be available for all who wanted it, the bottom line is that people like Brendon and his mother often have been left to fend for themselves. Scores of people in Maine are telling me similar stories. A veteran from Biddeford with a compromised immune system due to a liver transplant came to my Biddeford office asking for help. School nurses have contacted me frustrated with last-minute changes regarding vaccine delivery and availability.

What is the national strategy? Where was the plan? And as Senator Lieberman has said in his opening statement, why wasn't the plan altered when manufacturing problems first became evident? And those problems appear to have become evident in late June and early July, according to our interviews with the manufacturers.

Instead of false assurances, why wasn't the Federal Government explaining the challenges with the manufacturing process and distribution and revising and clearly communicating a new vaccine distribution strategy?

If I were to summarize the sentiments of so many Mainers and so many others across the country who have hit obstacle after obstacle in trying to obtain the H1N1 flu vaccine, I would choose one word: "Frustrated."

Parents are frustrated that they cannot get the vaccine for their children.

Doctors and nurses are frustrated because they cannot give their patients accurate timelines for vaccine arrival.

State and local officials are frustrated because they cannot plan a cohesive community response because the promised supply of vaccines often does not arrive on time—if at all.

Americans across the Nation are frustrated because they want to take recommended steps to help protect themselves and their family's health, but they cannot.

Let me cite another example across the country from Maine. The Web site for the Department of Public Health for San Francisco has a section called "Frequently Asked H1N1 Swine Flu Vaccine Questions." Let me read some of the questions and the frustrating answers.

Question: My pediatric office has live virus vaccine. When will they get the injectable vaccine? Since obviously the live virus vaccine is not suitable for everyone.

Answer: The Health Department has no way of knowing that, and neither does your doctor's office. All orders are being filled on a random basis.

Question: I go to an internal medicine doctor for my care. When will she have the vaccine?

Answer: This is unknown. At the rate vaccine has been trickling in, it could be in 1 to 2 months.

Question: Why does the doctor's office across the street from where I take my children have the vaccine, but my children's doctor does not?

Answer: Orders are being filled on a random basis. There is no way to predict who will get what and when.

The final question that I will read is perhaps the most poignant. Question: What am I supposed to do if I am in a high-risk category and I cannot find any vaccine?

Answer: Take comfort in the fact that you are not alone. It remains unclear to all involved when the full supply of vaccine will be in place, so please remain patient and calm and know that the whole country is experiencing the same wait.

What an awful answer to have to give to someone like my constituent who had a high-risk child with two autoimmune diseases and asthma and is searching the entire State to find a supply of the vaccine.

It is also frustrating, confusing, and aggravating to our constituents when we learn that while a high-risk veteran has been unable to get vaccinated at the Veterans Affairs (VA) hospital, terrorist detainees at Guantanamo Bay may be getting the vaccine ahead of Americans in priority at-risk groups. We learned that executives at

bailed-out banks, such as Goldman Sachs and Citigroup, may be getting the vaccine ahead of children and pregnant women.

Just this last month, this Committee held a hearing to examine the government's efforts, and as the Chairman said, there is much to applaud with the early identification and development of a vaccine. But when we asked about vaccine availability, we received rosy reassurances from the Secretary of HHS about the supply. She said—and I want to quote because it has not come to pass. Secretary Sebelius said, “By early November we are confident that vaccine is going to be far more widely available. There is enough vaccine, and will be, to vaccinate every American who wants to be vaccinated, and we are pushing it out as quickly as we can.”

Well, Mr. Chairman, it is now mid-November, and we know that supply production is still lagging behind those repeated assurances.

Only after our October 21 hearing did the truly dire nature of the vaccine shortage come into clear focus, and I join the Chairman in expressing great disappointment in the responses that we have received from Secretary Sebelius in reply to our specific questions. What we received in response were generalizations and non-answers.

The Administration needs to do a better job working with State and local public health officials who can then set attainable goals, and surely all of us should agree that the vaccine, while it is still limited, should be distributed to the most vulnerable groups.

Americans—like Brendon Stearns—deserve answers. H1N1 may well resurge, perhaps in a more powerful form, next year. In any event, we know well that this will not be the last pandemic that we face.

Thank you, Mr. Chairman.

Chairman LIEBERMAN. Thank you very much, Senator Collins. I appreciate that. I welcome the witnesses. Do you have a preferred order to go in?

Mr. GARZA. No, Senator.

Chairman LIEBERMAN. Is it appropriate to start with Dr. Schuchat? I want to just move across the table. We welcome you back.

Anne Schuchat, doctor and admiral, if I am not mistaken, is Director of the National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention. Thank you for being here.

**TESTIMONY OF ANNE SCHUCHAT, M.D.,<sup>1</sup> DIRECTOR, NATIONAL CENTER FOR IMMUNIZATION AND RESPIRATORY DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Dr. SCHUCHAT. Thank you, Chairman Lieberman, Ranking Member Collins, and Members of the Committee. I am really pleased to be able to speak with you today to update you on the Administration's response to the H1N1 pandemic. I am going to give a brief update of the situation and then go into more detail into the response and the vaccination situation, which I believe is the heart of the focus.

<sup>1</sup>The prepared statement of Dr. Schuchat appears in the Appendix on page 348.

Chairman LIEBERMAN. Right.

Dr. SCHUCHAT. As you mentioned, we did last week update the estimates of the full toll that we believe the virus has had in the first 6 months. We do not think the reporting of lab-confirmed cases really tells the whole story, so we are estimating 22 million people have been infected and ill since the first 6 months.

Chairman LIEBERMAN. So the big difference is that the previous estimates were just, as you said, based on laboratory-confirmed cases.

Dr. SCHUCHAT. That is right. What we have done is taken a number of surveillance systems and efforts to correct for under-reporting the accuracy of the lab result and so forth, and we have come up with this 98,000 hospitalizations, nearly 4,000 deaths, and as you said, tragically, over 500 deaths in children, probably.

Right now the H1N1 virus is still widespread in 46 States. In many States it is beginning to decrease, but it is still way above the estimates of what is normal for this time of year, and it is continuing to increase in the northeastern part of the country, where you both live.

So far there has been no change in the illness pattern. The majority of illness is in younger people. Many of the severe cases are in people with underlying conditions or in pregnant women. So far there is no change in the virus. It has not mutated to become even more virulent. The good news is the vaccine is an excellent match with the virus that is still circulating, so we expect high efficacy of the vaccines that we have.

But, unfortunately, influenza, including H1N1, is unpredictable, and we cannot tell you the trajectory, how much longer we will have this widespread disease, how many more waves will follow, whether we will have a substantial additional wave after the first of the year, which is what happened in 1957.

It is important, I think, to thank Congress for the incredible investments in preparedness that have made the rapid detection and the response that we have had possible. Without those investments, things would be much worse. We know that there are many places where there is room for improvement, but I do believe that we are much better off than we would have been without the years of preparedness investments.

On the poster and then in the handout that you have, I have tried to summarize CDC's role in the response, and you will hear from Dr. Lurie about HHS's broader role.<sup>1</sup> We, as you mentioned, identified and rapidly characterized the virus. We developed candidate vaccine strains that could be handed off to industry. We used our epidemiology and laboratory efforts both in the United States and globally to understand what was going on, how far this was spreading, and to develop science-based interventions.

We have had aggressive comprehensive science-based response with rapid deployment of the assets in the Strategic National Stockpile, life-saving antivirals, and other measures, including respiratory protection.

We developed and distributed laboratory kits to all of the public health labs in the United States and to 150 countries so that we

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<sup>1</sup>The chart referenced by Dr. Schuchat appears in the Appendix on page 361.

could understand what was going on abroad. That was all based on investments that had come through the preparedness resources. And we deployed field teams to provide technical assistance at home and abroad and continue to do that.

We issued science-based guidelines for key sectors, including mitigation efforts that focused on schools, businesses, and health care workers, including treatment with antivirals such as those in the Strategic National Stockpile, and also additional products that came to be available through emergency use authorization.

Communication and State and local support were key underpinnings to our response, and then, of course, one of the key pillars of the response has been vaccination. This has been an unprecedented effort to develop the strain, to prepare to carry out clinical trials, to develop recommendations for use, and, of course, to launch the voluntary program.

I share your disappointment in the initial production and the set of supply constraints that we have today. We have all been victim to the biologic processes of a slow-growing virus, and it really underscores the need for those long-term investments in vaccine technology and expanding production capacity. But production is accelerating and substantial amounts are becoming available, not as much as we want, but more every day.

Today, 48.5 million doses of H1N1 vaccine are available for the States to order. About a quarter of that is the nasal mist that you mentioned, which, of course, can only be given to healthy people 2 to 49 years of age.

We have prioritized for the use of this vaccine groups that were at the highest risk for disease or the highest risk to spread. The national standards were set by that Advisory Committee for Immunization Practices that you referenced, but we have been supporting State and local decisionmaking on the best ways to put vaccine in the path of the priority populations.

We know that States are carrying this out in a variety of ways. Thirty-four States so far have initiated school-located vaccination efforts. Virtually all of the States are providing vaccine to providers. Some are using lotteries to decide who gets the vaccine. Some have ethics boards. Some are focusing on the high-risk providers that serve the highest-risk children or adults.

We have heard of some success stories in the midst of all of this challenge. I have to say that the State of Maine has been doing an extraordinary job. At the end of this week they expect to have completed vaccinations at all 130 school districts. They have also provided vaccine to providers with those highest-risk patients—unfortunately, not early enough for many of the families who had to go through the nightmare that you described, Senator Collins.

We know that Connecticut, Delaware, and others really focused on the high-risk providers, hospitals, Federally qualified health centers, and others are now actually beginning to be able to provide some vaccine to retail venues which can reach additional people or to workplace clinics that can reach the high-risk groups while they are at work and not requiring them to leave work to get vaccinated.

This is definitely a State and city-run implementation effort. Our Advisory Committee reiterated in October, once we knew about the

supply shortages, that the State and local people were in better shape to sort out the subprioritization efforts and how best to reach the important groups.

It has been critical to use the vaccine doses as quickly as they become available and not have them sit on the shelf, and I really want to applaud the public health folks at the State and local level who have been working day and night to carry this program through.

I also want to mention safety. We are committed to a safe vaccine system, and although we do not expect any problems with this product, we are carefully monitoring the situation, working with external advisory groups and so forth, to make sure that if anything unusual occurs we are able to intervene promptly.

We have been working very hard across HHS and with other parts of the U.S. Government to make sure that the State and local health departments are in the best position possible to support prevention efforts on the ground. I think that this H1N1 pandemic really highlights the need for long-term investments in that infrastructure that is the front-line response system.

And just in closing, I want to say I will be happy in the questions and answers to address the specifics of the distribution system and really share the frustration that you describe. I wish that we had more vaccine and that it was much easier for people at risk to get vaccine.

Chairman LIEBERMAN. Thanks, Doctor. I am sure you do. I am sure you are at least as troubled as we are and as people in our States are when they cannot get the vaccine. We want to come back to it, but I want to know what you would do differently next time to try to avoid a similar crisis, particularly once the production was way below what the estimates of the need were.

Dr. Nicole Lurie, this is actually a good room to get sick in, if you want to—we have three doctors as witnesses. I am not suggesting anything serious, but there is a plethora—

Dr. LURIE. I thought you were commenting on my virus.

Chairman LIEBERMAN. Dr. Lurie is the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services, who will provide testimony, I hope, detailing the development and production of the H1N1 vaccines, including monitoring of manufacturers' timelines for vaccine distribution.

Dr. Lurie, thanks for being here.

**TESTIMONY OF NICOLE LURIE, M.D.,<sup>1</sup> ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Dr. LURIE. Great, and thank you so much for the opportunity to come and talk with you today about our efforts during this pandemic. I, too, would like to start by taking the opportunity to thank you for your continued support. It was really due to your foresight that we began rebuilding the vaccine infrastructure several years ago when we decided to pursue vaccine for H1N1. It turned out we already had pre-existing contracts with manufacturers already licensed in the United States, enabling us to get out of the blocks

<sup>1</sup>The prepared statement of Dr. Lurie appears in the Appendix on page 362.

quickly with vaccine manufacturing, and the right-hand side of that graphic<sup>1</sup> really identifies some of the investments that were made to make that possible.

I want to really start by just reviewing for you the role of my office in this, which is really four-fold.

First, our role is to coordinate across-department response and to work across the interagency, including with my colleague Dr. Garza.

Second, ASPR stimulates the development of and contracts for vaccines and antivirals.

Third, is to ensure that we can backstop States and communities when they get overwhelmed and request our help.

And, fourth, really importantly, is to stay prepared for any other emergency, not to take our eye off the ball during this critical time. And you will remember that we did respond to the tsunami in American Samoa in the middle of this.

I want to say that this H1N1 response has been a public-private partnership from the beginning. I think you have already highlighted the incredible speed with which vaccine was made, and I want to say that also would not have been possible without our partnerships with industry. But while modest amounts of vaccine came a little ahead of schedule, a combination of poor production yields, late completion of seasonal vaccine, problems with new filling lines, decisions in the home country of a manufacturer, all caused delays—and, frankly, repeated delays—in the availability of vaccine, but I want to stress not just for the United States but for the world. And the left side of the graphic,<sup>1</sup> the pieces in orange in that graphic go through the vaccine manufacturing process and show you really all of the places where things have gotten stuck along the way.

While we have all been, I think, really frustrated by the delays and tear our hair out each time we hear about another problem and another delay, I think from my perspective we have done our best to communicate directly with the American public each time we have learned of one of these problems. As said, now the number of doses that have been produced and distributed, as you heard, continues to grow steadily, and we continue to expect increasing amounts of vaccine in the coming weeks.

We remain incredibly vigilant here. We talk to the manufacturers every day. Right now we have full-time people at two of the manufacturing facilities just to monitor and assist, to give us a heads-up if any problems are occurring, and to help with on-the-ground problem solving. In addition, Secretary Sebelius and I have spoken directly with the chief executive officers on more than one occasion to identify opportunities to work together to speed the delivery of vaccine and, frankly, to be sure that there are not any arcane, bureaucratic obstacles in the way at our end to making that happen.

So while the delays are really frustrating to everybody—and we hear that, and it is frustrating to us as well—it is really the virus that is the real enemy here. I think as Dr. Schuchat said, and I think you know well, it continues to really reinforce the need to

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<sup>1</sup>The chart referenced by Dr. Lurie appears in the Appendix on page 385.

move forward to new technologies, to more robust manufacturing capacity, to more robust filling capacity so that, frankly, a virus of the future does not defeat us.

Although the focus of this hearing is on vaccines, I do want to highlight progress that we have made in antivirals. As you know, we now have the first ever intravenous antiviral available under emergency use authorization. We are procuring over 30,000 doses across three different types of IV antiviral drugs to treat critically ill in-hospital patients.

We have also been really focused on ensuring that the health care system itself—in communities—can remain able to care for people. The President's emergency declaration has enabled us to support hospitals and health systems that need to be decompressed with 1,135 waivers, and we stand ready to deploy Federal assets where necessary to support health care facilities. Our first Federal vaccination team is actually being deployed to Delaware next week to help with vaccination there.

We have partnered very closely with the private sector health care system—health insurers, pharmacists, big box stores, the American Medical Association (AMA), the public health community—to find ways to pay for vaccine administration so that cost is not a barrier.

Let me move on a little bit to some lessons learned.

First, as I said, the support of Congress has been really critical in helping us to strengthen the vaccine infrastructure, enabling us to respond quickly. But yet it is clear to all of us, I think, that chronic underinvestment in public health, whether in that infrastructure, at the Federal, the State, or the local level has real-world consequences. And I think we are seeing some of those. We cannot afford to let that happen again ever. And while we have made vaccine in record time without cutting any corners, in retrospect the original projections which were based on the collective experience with seasonal flu manufacturing and H5N1 pandemic preparedness manufacturing, were optimistic in the face of what proved to be daunting challenges provided primarily by Mother Nature and despite the best efforts of the Federal Government and our manufacturing partners.

Congress and the public have rightfully asked for projections about the numbers of doses, and we want to be transparent. But at the same time, we have to provide all of the caveats about the uncertain and changeable nature of these projections. In the face, again, of Mother Nature, this continues to be fraught with uncertainty.

A real challenge here, though, especially has been the fact that as messages get captured with shorter and shorter sound bites, you lose all the detail about all of these caveats and these contingencies. This has led to frustration for everybody involved. So as the supply improves and we incorporate early lessons now from the vaccination efforts—and I want to say that there have been a number of those, and each time we learn one of these lessons, we incorporate it, we pass it on to our partners in State and local areas. And so, they are able to work to do things, to get those lines shorter and to make it easier for people to have an easier time getting vaccinated as time goes on.

I do want to mention the past week because you talked about this week's projections. The storm that was the remnants from Hurricane Ida delayed shipment to one of the major depots and, frankly, nearly derailed vaccination campaigns in States from Maine to Alabama. I want to credit the staff at CDC and the office of the Assistant Secretary for Preparedness and Response that worked all weekend to be sure that vaccine could be ordered and shipped on Sunday night so that clinics scheduled for this week could go on as planned.

Importantly, we are far from done with the science and advanced development related to vaccines and with building manufacturing capacity in the United States. In other words, that underinvestment in advanced development is also chronic. And as you said, Senator, my fear is that when this is over, we will decide we do not need to worry about another pandemic for the next 30 years, and nothing could be further from the truth or be more dangerous.

I also want to point out that much of what we do today is relevant for any new threat we need to confront, whether made by Mother Nature or made by human beings. Despite these challenges, I think that much of what we have learned and we are continuing to learn through this pandemic and the investments we have made to address it will serve us well in confronting public health emergencies and threats for many years to come.

I, too, look forward to providing a more detailed explanation of the graphic, the timelines, and other matters during our question-and-answer period.

Chairman LIEBERMAN. Thanks, Dr. Lurie.

Finally, we have Dr. Alexander Garza, welcome back, Chief Medical Officer and Assistant Secretary for Health Affairs at the Department of Homeland Security. Dr. Garza will testify about the Department's actions since our Committee's hearing on October 21 and the Department's assessment of how States are managing the outbreak.

Welcome back. Thank you.

**TESTIMONY OF HON. ALEXANDER G. GARZA,<sup>1</sup> ASSISTANT SECRETARY FOR HEALTH AFFAIRS, AND CHIEF MEDICAL OFFICER, U.S. DEPARTMENT OF HOMELAND SECURITY**

Dr. GARZA. Thank you, Mr. Chairman, and good afternoon to you and Ranking Member Collins and the rest of the Committee today, and thank you for allowing me to testify here this afternoon.

Before I get started, I wanted to offer a quick thanks as well for my confirmation hearing this summer. This is the first time I have been able to testify before you, and I thank you for that.

The current H1N1 pandemic is a unique event. There is no ground zero. There is no location where it is most likely to make landfall. There is no discrete beginning or end, and although this pandemic will not destroy buildings, it can cause a lot of stress to our society, as you have mentioned. And although this hearing is focusing on vaccine, I wanted to discuss some of the Department of Homeland Security's efforts in dealing with the H1N1 pandemic.

<sup>1</sup>The prepared statement of Dr. Garza appears in the Appendix on page 387.

To this end, we have focused our efforts on protecting the people and the country from the effects of the pandemic. As you know, Senator, DHS has a dual mission in combating the flu. While we are intimately involved in the national planning and response efforts, we also work internally with our policies and procedures to protect our workforce so that they can continue to safeguard our country.

The principal tasks of the Office of Health Affairs (OHA) regarding the current pandemic are providing information, analysis, and advice to Secretary Napolitano, co-leading the DHS H1N1 planning effort, helping ensure that the DHS workforce is protected, and serving as the lead representative for the Department of Homeland Security in the interagency coordinating body.

Together with our interagency partners, DHS has led a strong Federal response. We have learned from our experiences and have implemented changes to help us both currently and in the future. The key lessons that I would like to describe are interagency coordination, planning, workforce protection, and communication.

The spring outbreak illustrated the necessity of strong interagency coordination. We have worked closely with our Federal partners, including my colleague Dr. Lurie at ASPR, with the Department of Health and Human Services, with the Centers for Disease Control and Prevention, as well as the Department of Education and the White House.

In addition to working horizontally across our Federal partners, we have also worked vertically with State, local, tribal, and territorial governments, as well as the private sector and faith-based communities in providing guidance. The DHS Office of Intergovernmental Programs conducts weekly calls and meetings with our homeland security advisers across the country, and National Protection and Programs Directorate (NPPD) coordinates with critical infrastructure representatives, and this is just to name a few of our efforts. And we will continue to collaborate and push information out to all.

As my experience in the Army has taught me, plans must be flexible enough to adapt to the reality on the ground. This Department has learned this as well. As we all know, plans never survive first contact with the enemy.

While we originally planned for a worst-case scenario of pandemic flu that originated outside of our continent, we quickly realized that this was not the case. Having plans flexible enough to adapt and maneuver to the changes of the current reality are imperative if we are going to meet future challenges.

Additionally, we tested our internal coordination and planning by conducting tabletop exercises that brought together the leaders across the Department of Homeland Security and which were actually attended by the Secretary as well as the Deputy Secretary in order to test our programs for the stress that H1N1 would place on our components. This provided an opportunity for us to identify how to meet our mission-critical functions while protecting employees during an influenza pandemic event.

As I mentioned earlier, DHS has a dual mission where one complements the other. Eighty percent of the Department of Homeland Security personnel are operational, and for comparison, this is

roughly the size of the Marine Corps. OHA and DHS have moved aggressively to ensure that our forces are protected. We have widely disseminated evidence-based guidance to our employees and posted it on our Internet sites. In addition, we spearheaded the acquisition, storage, and forward-positioning of our protective measures, including personal protective equipment and antiviral medications.

By performing these functions, we are helping assure that the threat of the current pandemic will not influence the security posture of this Nation. Because our job at DHS is to ensure a coordinated Federal response, information sharing is essential. OHA coled the operational planning team that served as a hub for the collection of data to present leadership a clear picture of what was occurring during the pandemic. In addition, our National Biosurveillance Integration Center led a modeling effort in the spring to get a better idea of what was possible with the resurgence in the fall, especially the impact on our critical infrastructure and key resources.

We recently shared this with our leadership as well as our partners at the State, local, and private sector. As a result of these efforts, we have partnered with Health and Human Services on further modeling efforts to understand the effects of the flu. As we move forward through the fall flu season, we will continue to build on these strong relationships formed with our partners across all levels of government and the private sector.

Again, I would like to thank you for the opportunity to testify before you today, and I look forward to answering any questions. Thank you.

Chairman LIEBERMAN. Thank you very much, Dr. Garza. We will do 7-minute rounds of questioning for Members of the Committee.

Dr. Schuchat, let me just start with the numbers here on the incidence of the virus, and as you said, you changed the method of calculating—in other words, going beyond laboratory confirmed cases. If my recollection is right, in the new projections or estimates you are making, both the incidence and particularly the number of deaths has gone up significantly from what originally had been thought to be the case. Am I right? And if so, what does that tell you as an expert in this about the incidence of H1N1?

Dr. SCHUCHAT. Since the beginning of the pandemic, we have tried to use approaches to surveillance that were appropriate to the resources available and the stage of the pandemic. So, initially, we were counting individual cases. It was very important for testing to occur in a widespread way so that we would know whether it had arrived in additional places.

At a certain point, individual case counting was no longer an efficient use of resources or an efficient use of the health care system, and so individual case counting was stopped, and we worked with the State health departments to identify other approaches to tracking the disease.

All the way through, we have been saying that reported cases, whether lab confirmed or based on other definitions, would be an underestimate of the true burden of infection. Many people do not seek care when they are ill. Many people who are ill do not get a test performed. Many people who get a test performed have a nega-

tive result because the tests are not 100 percent accurate. And then not all positive tests get reported into the various systems.

So, really, since the beginning we spoke about the measured burden and then the unmeasured burden, and we worked to find a science-based approach to accurate estimates. We released some estimates earlier this year about the disease from April through July and last week were able to talk about the first 6 months of the pandemic, and there came away with these numbers that were much greater than reported cases, but we believe much more accurate.

Chairman LIEBERMAN. Were you surprised when the numbers came in? They are pretty high. I was surprised, 22 million illnesses, 98,000 hospitalizations, more than 3,900 deaths, including, as we said, about 540 children.

Dr. SCHUCHAT. I would say that I was not surprised. I was sobered. But I also want to say that we have been taking this seriously from the beginning. Some people thought we were overreacting to this new threat, but I think the idea of a new strain of influenza that the population is susceptible to means that you can get these kinds of tolls. Even if the virus is not as virulent as the H5N1 bird flu strain or the 1918 strain, a new virus in a susceptible population can lead to large-scale illness. And that is really why we have had this focus on methods to decompress the health care system, have the sickest people cared for, rapid use of antivirals for them, but people with less severe illness were able to be cared for at home without clogging up the emergency departments.

So I think we have been taking this very seriously, so the numbers were expected for me.

Chairman LIEBERMAN. Let me go on to this main question, which is the lines, the frustration, and the fear of people not getting the vaccines. And I want you to respond. My theory on this—and I am just observing—is that the government, HHS, CDC, should have done a large national announcement of a reduced list of people who had to go out and get the vaccine and everyone else should stay home for a while when it was clear we were going to get fewer vaccines.

If that was not the case—again, you have spent so much time on this. You have got to be as frustrated and in some ways embarrassed as anybody else, more so about the problem with distribution of the vaccine. So is my theory right? And if it is not, what did cause this problem? Because it did not just happen. Something went wrong.

Dr. SCHUCHAT. Yes. You mentioned the just-in-case scenario with the smaller population.

Chairman LIEBERMAN. Yes.

Dr. SCHUCHAT. Our Advisory Committee met July 29, 2009, but they met again in October. We re-asked the question to them. Are the scenarios of supply that we are looking at now such that we really ought to go systematically nationwide for that smaller group? We also consulted State and local health department leaders, the Association of Immunization Managers. There was an active discussion at our public meeting of the Advisory Committee.

What we heard pretty consistently was leave the flexibility to the State and locals, let them decide whether to subprioritize—and a number did—or go broader.

We also had a bit of an unfortunate occurrence in the beginning of the supply that, the first week or two, almost all of the supply was the nasal spray. That does not stretch very far with the highest-risk group. It will not get a child with asthma. It cannot be used in pregnant women. We wanted to be able to use those doses.

We also heard clamors from many that they really wanted to do school-located clinics. They thought protecting children was important, and also slowing spread by protecting children would be important, and also children under 10 need two doses. So many States wanted to be able to move forward with the school-located clinics.

Chairman LIEBERMAN. Let me interrupt. So looking back, don't you think mistakes were made here? Because it did not work as you hoped it would. It is possible—I am a lay person. I know there are experts on the Advisory Council, but, my own reaction to this is that they were wrong.

Dr. SCHUCHAT. I think that looking back is very important, and we are also trying to look forward and learn. I think we are committed to continuous learning in this.

One thing I think we can look back and say was a mistake is some of our communication, that whether we meant to or not, I think we led expectations of availability to be higher than they have been, and so that I think can lead to frustration.

But I would say that, I have tremendous faith in the American public. I hate that people had to wait in line or that people have not been able to find vaccine. But our surveys tell us that those who looked for vaccine and were not able to get it, nine out of 10 plan to look again. And, fortunately, it is getting a little bit easier each day, although not yet at the point where demand and supply have gotten close enough together.

Chairman LIEBERMAN. All right. I appreciate that. And, actually, I think you used the word “mistake,” and it is important to acknowledge that here because this is going to happen again and we do not want to let the mistakes happen again.

I tell you, one of the things that, it seems to me, happened here is that this is a national problem, and there was a focus on national alerts about this, so that the fact that you gave the States some latitude did not really sink in nationally. And, of course, if you happen to live adjacent to another State where the distribution was different or even in another community in the same State where one set of parents could get the vaccine at their doctor's and the other could not—I mean, we have all had this in all of our families. I was hearing from my children who are trying to get vaccines for my grandchildren.

I think this is a case really where it would have been better to have a national answer and in this case not go for federalism—in other words, not let the States and localities make their own decisions on prioritizations—because everybody was focused on the national warnings about the disease and the urging to go out and get vaccinated.

Dr. SCHUCHAT. Yes, just briefly, I think that we did really feel that local and State experts and authorities were in a better position than we were in Atlanta or others were in Washington to know how to best reach the populations in their midst—some of them, as I said, going very heavily with the private sector providers, others making mass clinics available for priority groups, others using sort of a hybrid approach.

I think that the sense of trust and the sense of planning really needed to be closer to the community level. Whether we supported the States and locals sufficiently, we did give resources for communication so they could do messaging. I am not sure it was, as effective as it could have been.

Chairman LIEBERMAN. I do not think it was. My time is up, but I understand about the particular places of distribution. That is an appropriate decision for State and local public health authorities to make. But I honestly believe, looking back, that CDC or HHS, when it was clear that the production of the vaccine was going to be so much lower than expected and predicted, should have just nationally said, OK, you decide, States and locals, who is going to give it out, but here is the most at-risk population, 42 million, and this is who you have got to concentrate on first.

My time is up. Senator Collins.

Senator COLLINS. Thank you, Mr. Chairman.

Doctor, let me continue on the line of questioning that the Chairman has just begun. It is my understanding that in July your Advisory Committee met and it identified 159 million people that could be categorized in the priority group. Now, that is a very large number, and that was based on CDC's initial estimates that there would be approximately 120 million doses by October. Is that correct?

Dr. SCHUCHAT. Well, one clarification is that in the summer, when the Advisory Committee met and set the policy of that group, there was actually an expectation that everyone was going to need two doses of vaccine. So the number of doses is not directly translatable to the number we are looking at now, because, fortunately, it turned out that people 10 and up only need one dose of vaccine.

Senator COLLINS. Well, that actually makes the situation worse because if you were assuming that two doses might be needed for much of this population, then there is a far greater mismatch on the number of high-priority individuals, almost 160 million people, versus 120 million doses. So that is even a bigger mismatch. And that was the July 29 meeting. Is that correct?

Dr. SCHUCHAT. Yes. And let me give you a sense of where the Advisory Committee was coming from. Our Advisory Committee recommends influenza vaccine for about 263 million people, and about 100 million people get vaccinated each year with seasonal flu vaccine.

It was impossible to know what demand for vaccine would be like, but we rarely equate a size of a population with a number of doses. They felt that they wanted a broad priority group. They did not want to micromanage the risk groups because they felt that demand may be fickle. It may be different in New York City from Maine. It may be different in October from November. And so they looked at the epidemiology of who was getting sick, who was hos-

pitalized, who was dying, where was the social disruption, and focused on a group that was quite large, the 159 million group.

Senator COLLINS. But then what happens is the Advisory Committee, I believe in August, created a smaller priority group.

Dr. SCHUCHAT. It was actually at that same July 29 meeting. The publication was finally issued in August, but on July 29, they voted on both the 159 million and the 42 million groups.

Senator COLLINS. The larger group and the smaller group. My point is that the Advisory Committee in the summer had identified a smaller priority group of 42 million people at highest risk. That included pregnant women and children. These are the people that we really want to make sure are going to get the vaccine. And yet at the same time, you are starting to realize that there are manufacturing problems that are beyond your control, beyond the Federal Government's control, that are greatly reducing the production of the vaccine.

So we have already identified the priority group that is smaller, and we know the good news that most people are protected with just one dose of the vaccine.

I just do not understand why the Federal Government did not then instruct States and local public health officials to concentrate on this priority group. And I believe the American people will put the highest priority people first gladly. But if they are not getting a revised distribution plan from the Federal Government, you create chaos. You create the chaos that we have seen of clinics not having enough, of people standing in long lines, and people who need it most not getting it.

And I so agree with the Chairman's point. I do not understand why, when it became evident that there was a mismatch with supply and demand, the priority group was not clearly communicated and Plan B put into effect.

Dr. SCHUCHAT. We did a substantial amount of outreach that was targeted to the 42 million population, working with caregiving groups, health care providers, and advocacy groups that served the very children with disabilities, high-risk condition groups. We also were somewhat cornered by the availability of the nasal spray, as I say, which cannot be used for pregnant women, children with asthma.

One of the striking features of the pandemic was the effect on children. Every time a healthy child has been hospitalized, it has been very different for each family and for each community or school. I think it is important to recognize that the 42 million group does not include healthy school-aged children. And I know so many parents who have been really anxious to get their young children and older children vaccinated; they are not in the 42 million group.

I would say that each decision that has been made has been taken very seriously. We have sought external advice. We have tried to look at things in different ways. And I think reasonable expert people could disagree on the best way to go forward. We are trying to improve every day.

Senator COLLINS. I think one of the lessons here is that when we do run into these problems, we need to prioritize the distribution of supplies.

Dr. Lurie, in my remaining minute, I want to raise two issues with you. When I have talked to public health officials and other experts, they say to me that they believe HHS made mistakes in two areas that would have made a real difference in terms of increasing the supply. The first was the requirement that individual syringes be filled with the vaccine. The manufacturers tell me that took longer than if you had approved batches to be distributed and then syringes could be filled at the local level, that it was a lot more complicated for individual syringes to be filled.

The second issue that I have heard repeatedly—and I know it is more controversial—is the use of adjuvants, and it is my understanding that the use of an adjuvant in a vaccine can dramatically increase the supply of the vaccine since each vaccine dose requires less antigen, for reasons that I realize we do not fully understand. But it is my understanding that in the European Union the vaccine is being made with the adjuvant and, thus, the supply is more abundant.

So I would like you to comment on those two decisions because from what I am hearing they would have had an impact on supply.

Dr. LURIE. Sure. Well, let me take each of them in turn.

First, with regard to the prefilled syringes, we did contract for a mixed supply of prefilled syringes and what are called multi-dose vials, the biggest bulk ones. As soon as we became aware—and that was pretty early on in the season before most vaccine was even being put into vials—one of the things we did was say to the manufacturers our priority is to get the most doses out fast. And so what that meant was, first, taking all of the available vaccine, the antigen you had, and putting it in those multi-dose vials to kind of saturate those filling lines; and then if you had stuff left over, go ahead and continue to fill the prefilled syringes instead of letting them lie fallow because you could get more doses out with that combination than with just the prefilled syringes.

So while you are right, it takes longer to fill a prefilled syringe than a multi-dose vial, I think in the long run everybody was asked to do those multi-dose vials first so that we could get as many doses out as possible. And, frankly, some of the manufacturers changed plans early on after we had the discussion about that to say how do you get as many doses out as possible.

And so while I hear that, I guess I do not think that it has contributed substantially to a shortage. At the same time, we need to have sort of an array of products out there that are acceptable to the kinds of choices that different people want to make.

Let me address the use of adjuvant because I think it is a really important question on a couple of fronts.

First of all, from the beginning, we sat down and have done this whole huge decisionmaking set of matrices or trees, and one of the really early things we said was at several points along the way we are going to have to decide if we want to use an adjuvant. And we said, well, what would be the early warning signs that we would need to use an adjuvant and what would make us go there. And at very regular intervals we have revisited that. So the early warning signs would be if the disease got worse, if people did not have a good immune response to the vaccine, or if there were not enough doses.

Every time we have had a decrement in projections, we have gone back, and we have looked at those decision trees and those triggers and convened senior scientists at the highest level to say should we move ahead with adjuvants. And every time the answer has been no, for two reasons. One is if we shifted to adjuvants, it would take a lot of the unadjuvanted vaccine out of the system while we made that shift. And two, as I think the public's confidence in vaccines in this country is just not as robust as we want it to be. The adjuvants would be a new vaccine. They might have to be used under an emergency use authorization. And so we did not really want to rock the public's confidence in a new vaccine.

A last point I want to make—and I think I said it in my testimony—this is a worldwide problem. Even with adjuvanted vaccine being licensed and available, we are still one of the very first countries to mount a large-scale vaccination campaign. Most developed countries have not. And we have distributed, even with unadjuvanted egg-based vaccine, more doses to be administered than any country in the world. So as frustrated as we are with the vaccine supply—and we are all really frustrated—I think it is just really important to keep that perspective.

Chairman LIEBERMAN. Thanks, Senator Collins.

I noticed a column in the *Washington Post* today by Anne Applebaum, and it speaks to the global confusion, if you will, about the problem. And I think when this is all over—and hopefully it will be before long—it is not just the U.S. Government but the World Health Organization that has to go back and take a look at how this all developed. Again, part of it is the global nature of media today and the way in which it portrayed the outbreak. This is serious and this is a real disease. Obviously, it has killed almost 4,000 people here in the United States in the last 6 months. But the media coverage created a kind of panic in some countries around the world, which makes our lines seem relatively mild. But they weren't mild for people who were waiting in them.

The Senators in order of appearance: Senators Kirk, McCaskill, and Carper. Senator Kirk, thanks for being here.

#### OPENING STATEMENT OF SENATOR KIRK

Senator KIRK. Thank you, Mr. Chairman, and thank you for the timeliness and importance of this follow-up hearing.

Like my colleagues, we had a promise of some 3.5 million doses to Massachusetts by this time. We have 900,000, I think, that have been distributed, so it is roughly 25 percent of what is needed at this time. And from what I understand from the testimony in the earlier hearing, in large part what your Departments tell us about what will be available is dependent on what the manufacturers have estimated. And I am wondering whether—in addition to site visits and monitoring and so forth—do the Departments have the ability to develop an expertise where they could make their own independent analysis in something like this? And if so, how is that applied? And if not, should we develop that expertise so we are not just totally dependent on the word of the manufacturer and they say this is what they have told us so, America, this is what you will get?

Dr. LURIE. I think it is a really good question. What I would say is that in our Department and in the Biomedical Advanced Research and Development Authority (BARDA), we have a really professional staff, many of whom came from the vaccine industry and I think have a pretty good sense of how all the supply chains work. We track every single lot of vaccine and are able to watch it in the pipeline.

That said, that early part, growing the vaccine and getting to those early doses, I think was the biggest problem. As we watch it come through the pipeline, I think we have pretty good visibility on what goes on with it, but I do want to say, per that schematic over there, you do continue to run into problems with production lines or at the end, even if you ship stuff to CDC and a temperature sensor goes off or a box breaks open in the truck, that makes you have to pull that amount of vaccine out and test it to be sure that it is still safe and effective before you can release to the public. So while we watch it, we cannot necessarily change it.

That said, one of the things that we have been really working hard on in our partnership with the manufacturers is additional ways to communicate about the vaccine supply. We are working with them to see if we can put out, public information by manufacturer, or by product numbers.

I hope that we will get to a point soon where we figure out how to do that so that we can provide an additional level of transparency for the public. But as I said, right now we have people in the plants, and I actually feel quite good about the communication that the manufacturers are having with us, sometimes multiple times a day.

That said, things still go wrong—not that we do not always know about them, but there is not an easy fix. But I very much take your point about forecasting and projections. I think the best way to do that is to have a more reliable way of making vaccine so that we are not dependent on the vagaries of growing virus in eggs.

Senator KIRK. Another question going to dependency, if you will, and that is—I mentioned this in the prior hearing to the Secretary—that four out of the five suppliers, as I understand it, are offshore. And I am wondering whether there really is serious thinking and planning about dealing with that issue.

We know in the instance of one of the suppliers, in Canada, quite understandably, said Canadians first and are taking care of their population. I did not know whether that was in the thinking and the estimates that were initially projected, that Canada might do that or whether you knew they would. That is sort of one question, but a side question.

The larger question really is whether the Administration and the health professionals are thinking about what we should be doing to encourage development and manufacture of these vaccines in the United States.

Dr. LURIE. I think it is just a really great point, and I might want to make a clarification first; that, early on we learned—it was actually the Australian Government that was experiencing a really severe first wave that said Australians first. And as soon as we knew that, we were able to say to the American public we are

going to have a lot fewer doses early on than we thought because of that.

That said, I think BARDA is in about year 3 of a 5-year strategic plan to modernize vaccine manufacturing. We have done a lot of retrofitting of facilities just to be ready for this one. A new cell-based manufacturing facility is going to open. Many of us are going to the ribbon cutting next week for a new Novartis facility that I think will be able to start making seasonal flu vaccine in 2011. It is only going to get us to half of the required doses we think that we might need to surge, and I do not know that cell-based vaccines are the end game because they still require virus to grow.

So we actually want to go ahead and make a mid-course revision to our 5-year strategic plan to think about even more modern science, even more robust manufacturing capacity, more advanced development. We are supporting very innovative manufacturing techniques, for example, in a company in Connecticut that is making recombinant vaccine in insect cells and others, and a lot of things that really show a lot of promise. But we have to get to domestic issues, say, robust, fast manufacturing capacity in the United States. We are taking this very seriously, and we very much look forward to further partnership with this Committee as we try to move that forward.

Senator KIRK. Thank you. Maybe one more question, Mr. Chairman?

Chairman LIEBERMAN. Go right ahead, Senator Kirk.

Senator KIRK. This is perhaps to Dr. Schuchat, and it is a question that has been written about the hybridization and the possibility, the "what ifs" if this particular flu should cross-pollinate, or whatever, with the bird flu.

Can you give us any thoughts about that? Is that a realistic possibility? And, in any event, will we be prepared for something like that?

Dr. SCHUCHAT. Influenza viruses change and they reassort. They can combine between viruses. Right now, the world is seeing a very transmissible virus in the 2009 H1N1 strain, and we still do have a very severe virus in the H5N1 bird flu strain. It has not figured out to be efficiently transmitted, but it is very fatal. Two-thirds of those infected with the H5N1 suffer death.

There are parts of the world now where both strains are circulating, the H5N1 primarily in birds and H1N1 in humans. So that idea of reassortment is not science fiction. That could actually happen. But if that does not happen, we still have the real probability of future pandemics, whether they are H5N1 derived or H1N1 or the H9 strain. Influenza is out there, and really the seriousness with which the Committee has been taking pandemic preparedness in the past just needs to be reinvigorated.

Some of us wish that now that we are having one it would mean we have 30 years off, but, unfortunately, I do not think we do. And so everything we can learn about preparedness from this, to be better able to cope if we had a more severe virus or if we have one where the circumstances are even more grave than what we are seeing now.

Senator KIRK. Thank you. Thank you, Mr. Chairman.

Chairman LIEBERMAN. Thanks, Senator Kirk. I appreciate it.

**OPENING STATEMENT OF SENATOR MCCASKILL**

Senator MCCASKILL. Thank you, Mr. Chairman, and I would like to formally on the record thank the Ranking Member for my pork hat. After I tried to make a very big point of the fact that this virus had nothing to do with the delicious meal of pork in our country, the Ranking Member was kind enough to send me a pink hat that points out my love of pork—the kind you eat, not the kind you appropriate. [Laughter.]

So I thank the Ranking Member for that.

Senator COLLINS. My pleasure.

Senator MCCASKILL. I decided to do a little secret shopping today in my office in preparation for this hearing. After reading the Chairman and Ranking Member's letters that were sent,<sup>1</sup> I think yesterday, I was concerned and so I asked some members of my staff today to call around Missouri and see what would happen if they asked about the availability of the vaccination. I had women in my office do it, and I said if you are asked, say you are pregnant. And it really was surprisingly a good exercise. We called seven different communities of various sizes, including the two major metropolitan areas, some very rural areas, and in between.

Almost all of them did the appropriate checklist about risk factors when we called, and once it was determined that this was a woman who was pregnant, three of the seven that we called made available today or tomorrow a vaccination. Two said this week they would have clinics. One said in 2 weeks there would be another clinic. And one said you need to check with your doctor or your local pharmacy.

Now, in all of them, they did say to us, "You should check with your doctor first." So it is clear to me that what the local and State health organization in Missouri is doing is they are distributing part of this to the doctors' offices, and they are holding on to part of it for their own clinics. And I think in fairness, I think that can be confusing to people. Now, should I be going to the clinic to get the vaccination or should I be calling my doctor?

We got pretty clear guidance on the phone when we called today, and I was pretty impressed that we got as clear a guidance as we did. But I take it this is totally a local decision as to how they are distributing this virus between doctors' offices and hospitals and local health-based clinics.

Dr. SCHUCHAT. The State health departments or in four large city or county areas are the ones doing the ordering. Many are working with their local health departments, and most are working with the provider community. They may have the local health departments enroll the providers, or they may be doing it centrally at the State level.

We do know that we have had, I think, 116,000 distinct shipments of vaccine from the central distributor to date, and they have gone to a variety of venues, to the local health departments, hospitals, doctors' offices, and so forth.

One challenge for the provider offices is the minimum shipment of 100 doses, and so some of the providers' offices are not able to use 100, and they are asking for smaller amounts, so there is a lit-

<sup>1</sup>The letters referenced by Senator McCaskill appear in the Appendix on page 409.

tle bit of breaking up amounts to get them their supply or sharing between practices. But we do believe right now that a substantial amount of the vaccine has gone to providers' offices.

In some places, there has been tremendous interest in signing up to be a provider for the H1N1 vaccine, but in others it has been a mixed uptake. Providers' offices are really busy, lots of people who are ill. For obstetricians, it is not always the usual thing. In many States, there has been great turnout by the obstetricians to be providers, to be able to give vaccine to their pregnant patients. But in other areas, the providers have had to say, "We are not going to be able to handle it. We do not have the right kind of refrigerator storage. We do not want the vaccine to spoil. But here is the hospital that we are partnering with. Here is where you as my patient can go to get your vaccine."

Senator MCCASKILL. I am confused, though, who is making that decision. I mean, I think the problem here, Dr. Schuchat, is, who is deciding whether a doctor's office is getting it and who is deciding whether the Jackson County Health Department is having those doses for a clinic that they advertise and is open to the public based on risk groups?

Dr. SCHUCHAT. Right. Well, at the CDC level we have advised here are the priority populations, these are the groups that need to be reached. At the State leadership level, they are designating the strategies. Should we focus on providers? Should we have a mix of health departments and providers? Part of it depends on the fragility of the health care system in that State. Is the provider community able to do this? Part of it depends on the robust public health infrastructure—

Senator MCCASKILL. OK, so it is the State health department that is making this decision?

Dr. SCHUCHAT. Absolutely.

Senator MCCASKILL. It is not being made at HHS. It is not being made at CDC. It is not being made at the Department of Homeland Security. The State health directors are deciding where the dosage that is going to their State is actually landing.

Dr. SCHUCHAT. That is right, and a lot of them have been updating their plans. They have identified plans, and then they have realized, well, we are going to need to make a few more venues available because we are getting calls and people are not able to get it from the ones we have set up. But they are in the lead on the implementation. That is right.

Senator MCCASKILL. Of the 160 million that were identified at the very beginning in the risk groups, how many do we anticipate will actually get—let us assume that we did not have a problem in the private sector with the availability of as much vaccine as we had been told we were going to get. I mean, the government was clearly told by the private sector they were going to get more vaccine than we got. Let us assume for a minute that there was no problem with the supply and that there was plenty of vaccine out there.

Best-case scenario, what percentage of that 160 million based on previous influenza problems in this country did you anticipate would step up and get the vaccination?

Dr. SCHUCHAT. I will give you two figures. For seasonal flu, it is about a third of people that step up, but we have been doing surveys throughout the summer and fall and find right now that up to 50 percent of people in those groups are interested in being vaccinated or having their kids vaccinated. There is a group that is distinctly not interested, and their principal reason is they do not think this is a serious threat. But of the group that is interested there, it is pretty steady that they are remaining interested. We know, though, from a lot of behavioral surveys that intent to take a behavioral action is different than actually following through with it. And, of course, the easier we can make it for people, the more likely they will be to follow through.

Senator MCCASKILL. So if we get 80 million people vaccinated in the at-risk groups, you are going to consider this a great success?

Dr. SCHUCHAT. I regret every person who has waited in line and not made it through, and I think the ease with which people can be vaccinated is an important metric as well.

Senator MCCASKILL. That is fair enough.

Let me talk about the military for a minute, and Wall Street. I am assuming the decision to give any vaccinations to major companies in New York was made by the city of New York?

Dr. SCHUCHAT. The city had a plan of how to distribute their vaccine.

Senator MCCASKILL. And was there any role at all for the Federal Government in that decision?

Dr. SCHUCHAT. No. But we are aware that their decisionmaking was—they had a first tier, which was hospitals and provider offices and the community clinics, and a second tier that included employer-based occupational health clinics, which is a place where a lot of adults in the workplace are vaccinated. That was not their first tier. It was a lower tier. But it was with a distinct provider agreement signed saying this will be for priority populations—pregnant women, parents of newborns, and so forth.

Senator MCCASKILL. It just was really weird that a company on Wall Street would get the same number as a hospital. That looked horrible. It made all of us really mad.

Dr. SCHUCHAT. Absolutely, and based on the information that I have seen, most hospitals got a lot more vaccine.

Senator MCCASKILL. A final question about the military. It is my understanding—I think we have two members of the military here that can speak to this. It is my understanding that the Department of Defense controls all the vaccinations for the military and that the armed forces are, under their directive, required to be vaccinated first, and that it is only after 90 percent of the forces are vaccinated that we even get to civilian personnel within the military, and only after 100 percent of the forces have been vaccinated and all of the civilian personnel would we ever get to any detainees everywhere. Is that correct?

Dr. SCHUCHAT. Yes. I am actually wearing the uniform of the Commissioned Corps Public Health Service, but that is correct.

Senator MCCASKILL. Close enough. [Laughter.]

In government work, close enough, right? Unfortunately. Is that correct?

Dr. SCHUCHAT. Yes.

Senator McCASKILL. So the rumors out there that we are supposedly giving the vaccination to anybody at Guantanamo that is being detained is just not true?

Dr. SCHUCHAT. You are right.

Senator McCASKILL. Thank you. Thank you, Mr. Chairman.

Chairman LIEBERMAN. Thank you, Senator McCaskill.

Senator Carper, with an amazing sense of timing, has come through the door at exactly the moment I was otherwise going to proceed. Senator Carper.

Senator CARPER. Thanks, Mr. Chairman. That was pretty good timing.

Our thanks to each of our witnesses for joining us today and for trying to explain what is going on here and what you all are trying to do to expedite the situation and maybe what we need to do to help.

Let me just ask this, and you may have covered this already in earlier questioning. But we have been asking you what you are doing and what our country is trying to do to expedite the availability of the vaccine for people throughout our country, particularly on a most urgent basis. What do we need to be doing on the legislative side? Anything? I think we have appropriated money. Hopefully we have appropriated resources. What else do we need to be doing?

Dr. LURIE. I think that is a great question. Thank you for that. I guess I would say that there are a couple of things that you could help with, and I very much, again, want to say how grateful we are for the support to date, both on the manufacturing side and in response to this pandemic, not only so that the Federal Government could buy vaccine for people, but also to support public health on the ground, which you know has been really struggling because of the kinds of cutbacks in Federal, but also in State and local budgets. So as we talk to public health people on the ground, their workforces are down by about a third, and they are trying to really struggle with this pandemic.

So this whole experience has told us that it is really time to think seriously about how it is that we revitalize public health at all levels and how it is that we revitalize our public health infrastructure.

So I think a lot of what we would love to talk with you about going forward is very much to look forward, how to do that. How do we not get in this situation again? We have talked about it with the advanced development of vaccines and countermeasures. We have talked about it with manufacturing. We need to have that same conversation about the rest of the public health infrastructure, whether it is about surveillance, whether it is about public health on the ground, or whether it is about the fact that while we have a good system to buy and distribute vaccine for children in this country, we have no system to do that for adults. So going forward, I think that there is an awful lot that we take away from this that helps us be a lot better prepared.

Senator CARPER. All right. Thanks very much.

Anybody else with a real quick response? Or I will go right to my next question. Anybody?

Dr. GARZA. Well, I will put in a plug for Homeland Security. I think what H1N1 did illustrate is that the health effects to national security are real. And although DHS does focus a lot on terrorism and overt acts of aggression against our country, this is a primary example on how health effects can and do affect national security, and those issues need to be taken into account when we are looking at planning, funding, and issues such as that.

The Office of Health Affairs is a fairly small office. However, we carry a big mission: Taking care of our forces as well as planning for disasters and responding to the health effects. And I think the pandemic has brought that to the forefront.

Senator CARPER. OK. Thanks very much.

I think the Department of Health and Human Services last month announced contract awards, I think for up to about 120,000 treatment courses of intravenous antiviral drugs, known as IV, to help treat hospitalized 2009 H1N1 influenza patients. The IV alternative has been proven, I am told, to be very effective in treating sick people.

Could I ask each of our HHS witnesses today to briefly detail the deployment plan for IV vaccines? And just to let us know, is there a plan to order any more of the initial 120,000?

Dr. LURIE. Let me make a quick clarification here. We have right now procured about 30,000 doses across three different kinds of vaccines. As you know, the vaccine is not yet—I mean, the antivirals are not yet licensed. They are available under an emergency use authorization because they have not gone through the full array of clinical testing to know that they are really safe and effective.

So one of the things that we need to do through this is to learn just how effective they are so that if they are effective, they can move forward on a pathway to full licensure.

In the meantime—and, frankly, I think learning from a lot of our experience with distribution; this is an example where we took experience and turned it around to immediate learning—we have done a couple of things. We have set up a Web site that is open 24 hours and a telephone line that is open 24 hours so that any clinician in the country who feels as though they need to have this antiviral for their patients can call. It is managed by a distribution site, and there is overnight shipping so that it can be there within 24 hours. So far, there have been orders for—as of yesterday, I do not know as of today—634 treatment courses. So that is really right now the distribution system.

Should there be a really big demand for more intravenous antivirals, we will go ahead and procure more. But we are monitoring carefully that burn rate so that we are sure that we do not run out.

Senator CARPER. All right. Did you want to add to that, please?

Dr. SCHUCHAT. Yes, just to say CDC is managing that Web ordering system, and we have been getting orders through the weekend and at night and are able to commit through the vendor that shipment should arrive within 24 hours of order, usually much earlier, depending where it is getting shipped. This is an intravenous antiviral, and so it is primarily critically ill people in intensive care

units that are receiving it. But it has been stood up very quickly and tried to be as responsive as possible to the health need.

Senator CARPER. All right. Thanks.

There are reports that if the H1N1 pandemic grows more potent and ubiquitous throughout our communities, we as a Nation could face a serious drop in blood donations. While it is proven that a low-level flu strain cannot travel through the bloodstream as the West Nile virus does, for example, some scientists feel that a more potent H1N1 flu could infect our body's circulatory system and prevent people from donating blood. This, of course, could create a serious problem for hospitals who rely on these blood donations for minor to serious medical procedures, as you know.

Could either of you perhaps comment on this and if you have a battle plan for if the H1N1 strain morphs?

Dr. LURIE. Well, let me first start by telling you that we monitor very carefully the country's supply of blood, and I get a report on that every week. One of the things that we have noticed coincident with this pandemic is that the supply of blood, which is usually about 8 days in most hospitals, is down to about 6 days. Whether it has anything to do with H1N1 or canceled blood drives or any other kinds of things, I do not think we know cause and effect, but we are keeping a very close eye on it.

We also have, I believe, very good ways to look at the country's supply and to be able to move blood from one place to another were that to happen. But despite the fact that it is down to 6 days, we are not aware of any shortages.

Is there a battle plan? I think any part of preparedness requires a battle plan to be sure that blood as a critical resource is always available as needed. And, the battle plan really means stepping up blood donation and calls for blood donation, in which case, the American public is usually very responsive. To prepare for that, the CDC has issued guidance for blood donation centers to help them figure out how to have blood donation go on safely and without transmitting the virus among the people who work there or the people who choose to give blood.

Senator CARPER. All right. Thanks. Thank you both. In fact, thank you all very much.

Thanks, Mr. Chairman.

Chairman LIEBERMAN. Thanks, Senator Carper, for those questions. We will do one more round for Senator Collins and me.

I mentioned in my opening statement about the two numbers that were going the wrong way, the way we would not like to see them go: The number of cases of H1N1 going up, and understand that part of that is the recalculation; and then the vaccines available going down. But you have reassured us, and I just want to come back to that, Dr. Lurie, the explanation for the drop in the availability of vaccines last week was not a problem in the manufacturing but, according to your testimony, was the result of the hurricane and the distribution problems. Am I right?

Dr. LURIE. Let me say that it was two-fold. The way we do these projections and allocate is that we have a cutoff for when vaccine has to arrive at a warehouse, let us say Wednesday at 2 o'clock. If it gets there at 2:01, it gets counted for next week.

Chairman LIEBERMAN. OK.

Dr. LURIE. And so one of the things that happened was, because of the hurricane, some of the vaccine manufacturers' insurance companies did not want them to ship, and they did not want to take that risk of shipping and destroying their cold chain driving through this. And some of the vaccine got there late, and that is why when we woke up—or when we heard on Friday that there was potentially no vaccine to be allocated—we first heard from Maine, then from Massachusetts, then from others—we said, well, we know that their vaccine is there; it just did not get in under the wire, let us stay open this weekend and allocate it.

A second thing had to do with some doses of vaccine that—remember how I said at that last stage, when you ship, if a temperature sensor goes off or a box opens?

Chairman LIEBERMAN. Yes.

Dr. LURIE. So a second thing that happened was that for some vaccines some temperature sensors went off, and so they could not go ahead and distribute those vaccines right away, but they had to be sure, in fact, that those vaccines were still safe to be able to use. So that is what happened.

Chairman LIEBERMAN. So no new problems within the manufacturing chain.

Dr. LURIE. That is right.

Chairman LIEBERMAN. Other than what you have said about weather delays along the way, we can anticipate—I am not going to ask you to predict another problem—a pretty steady production now in availability of the vaccines, increasing every week. Obviously, we have a long way to go until we get to the 160 million of the initial group at risk.

I have forgotten the facts on this, but I am not sure—and I ask you now—whether we had as many Federal employees—I presume HHS or maybe CDC—in the manufacturing facilities as we do now monitoring activities there. Is that one of the lessons we have learned in this? In other words, am I right that we have more people on site now from the Federal Government?

Dr. LURIE. That is correct.

Chairman LIEBERMAN. So would you say that next time we get into this, that will be something that we will do? Or maybe we will just keep our representatives there from now on.

Dr. LURIE. I would say it depends. I think certainly throughout the rest of this or until things even out and there is really a very ample supply of vaccine and we understand that things are stable, we very much want to keep Federal employees at the manufacturing facilities.

As I said, we have talked to them every day. We do frequent site visits. It has been helpful to have people on site.

Another way it has been helpful to have people on site—and it is not related to manufacturing—is to have representatives from State and local health departments and the Association of State and Territorial Health Officials and National Association of County Health officials actually embedded in the operations center at CDC so that there is another level of what is going on, what do you expect, how do you communicate that back.

So I think at every step along the way—more people on site, more exchange, more transparency is better.

Chairman LIEBERMAN. All right. Well, that is an important lesson learned, and I appreciate it.

Let me go back to the intravenous antivirals, which I asked several questions about at the last hearing. The first thing I want to do is say thank you that the Food and Drug Administration did issue an emergency use authorization. And for people in the room or watching on TV, as I have learned as we have gotten into this, the IV antivirals are needed for the people with H1N1 who are the most sick, usually in intensive care, and, therefore, cannot take the normal antivirals by mouth and so have to have IV medication. So I appreciate very much that was done.

I was interested in how you are distributing them. I want to urge you, as I did last time, particularly because of the problems we have talked about with the vaccine, that you really stay on top of it to make sure that we do not come to a point where there is a shortage of the IV antivirals because that would be the worst of all because these are the most seriously ill patients, obviously, and it literally could be life or death if they do not have it.

Dr. LURIE. You have that commitment.

Chairman LIEBERMAN. I appreciate it.

Following the CDC reports, as my staff does, I note, sadly, that last week 35 children died of influenza in hospitals, which was up from 28 the week before, as we mentioned earlier, a total of approximately 540 children. I wondered if either of you know whether any of those were treated with the IV antivirals.

Dr. SCHUCHAT. I do not have that information. I know that of the children that we are seeing who die, about two-thirds have underlying diseases.

Chairman LIEBERMAN. Right.

Dr. SCHUCHAT. Some die at home. They do not actually make it to the hospital. But we are collecting additional information. So I do not know yet whether any of those children got the medicine.

Chairman LIEBERMAN. OK. To the extent that you can find that out—you have other things to do—I would appreciate just having an answer to that for the record.

Dr. SCHUCHAT. Sure.

[The information follows:]

INFORMATION SUBMITTED FOR THE RECORD FROM DR. SCHUCHAT

CDC does not track specific patient outcomes related to administration of antiviral drugs, and therefore does not have the information on how many pediatric patients died after receiving IV antiviral drugs. Based on data from the Emerging Infections Program, among hospitalized laboratory confirmed pediatric patients between September 1 and November 24, 85 percent of patients received the antiviral. That compares to 58 percent during the spring wave (April 15, 2009-August 31, 2009) and 17 percent during the previous season (2008–2009).

As of December 13, 992 requests to CDC for IV Peramivir doses have been filled, including 89 requests for pediatric Peramivir.

Chairman LIEBERMAN. I am going to stop at that point and let you go ahead, Senator Collins, because the vote has just been called on the floor. Thank you.

Senator COLLINS. Thank you, Mr. Chairman.

I am just going to bring up one final issue in light of the vote beginning. Dr. Garza, I know you thought you might get off scot free at this hearing. [Laughter.]

And I just could not allow that to happen at your first appearance.

Dr. GARZA. Thank you, Senator.

Senator COLLINS. I knew you would appreciate that.

You have some responsibility in this area for making sure that State and local public health agencies can handle a pandemic or a bioterrorism attack. In other words, DHS in general has a responsibility for assisting State and local governments in their preparedness and response capabilities. That is why we have appropriated literally billions of dollars in homeland security grants to help improve the preparedness at the State and local levels.

Dr. Schuchat mentioned that the State of Maine has done an excellent job—and it has, and I am very proud of that—and one reason is they had a plan in Maine to use the schools as a basis for the clinics. And I believe every single school in the State of Maine participated. That gives you a great distribution method, and I think a lot of other States could learn from Maine's experience.

But then we have what appears to be the situation in San Francisco, a much larger public health division than the whole State of Maine would have, where we have answers being given on their Web site saying orders are being filled on a random basis, there is no way to predict who will get what and when. That to me is an appalling answer to someone who has a child who is at high risk and needs the vaccine.

My point is that as we found with our investigation into the response to Hurricane Katrina, there are huge variations in the capabilities at the State and local level, and I can see Dr. Lurie is nodding her head in agreement.

So when we are through the peak of this pandemic, what is DHS going to do, working with HHS and the CDC, to evaluate the response at the State and local level?

Dr. GARZA. Well, I would say even before the pandemic is through that DHS has been working together with HHS in evaluating State plans, primarily through the Federal Emergency Management Agency (FEMA) which partnered up with HHS at the regional levels to ask questions of emergency managers and to review their plans and evaluate whether there are any gaps that need to be filled, were there any issues that needed to be resolved.

Furthermore, FEMA has worked together with HHS to provide any logistical support should that be needed for vaccine distribution or any other issues related to the emergency response.

Fortunately, it has not risen to that level where we have needed to interact at that level, but they have done a tremendous amount of work in working with our partners throughout the interagency to be prepared.

If I may, ma'am, one success story I believe that you mentioned in an earlier hearing with Secretary Napolitano was Bates College, particularly the Metropolitan Medical Response System (MMRS) team, which was requested to come up and assist with the vaccinations since they had a large vaccine allotment and not enough people to do that. But that is precisely the way the system should work, that they requested the MMRS team to assist them. The request went through Emergency Management, it was approved, and within 2 days a team was sent up there to vaccinate the students.

And so if I may, I would say that is one example of a very good success story and how DHS is assisting.

Senator COLLINS. It is, but we need to learn from this experience, and when we have a major public health department saying it is all random, it should not be all random. It should be prioritized. And I still share the Chairman's view that it would have been fine to leave it to State and local governments regardless of their capabilities if there had been plenty of vaccine. But once we realized the vaccine supply was falling far short, I believe the Federal Government should have stepped in and set the priorities to ensure that those at highest risk were being served first. And I do believe—just as you said, Dr. Garza, that the best of plans always collide with reality, I do believe that we need a thorough evaluation of the preparedness at the State and local levels. It does vary enormously because some States devote a lot of resources and some States do not. Some States are making good decisions, and some States are not. And that applies to big-city health departments as well. So I hope that will be done.

Doctor Schukat, I can see you want to say something—

Dr. SCHUCHAT. Yes, I just wanted to respond to two points.

One is we are not waiting for States or cities to fail. We are working very actively monitoring the ordering, understanding what is going on, offering assistance, and working on some of the missteps that we believe may be happening in some areas. As you heard, we have liaisons from the city and county health agency and the State health officer agency in Atlanta, and we are working daily with the States to help them succeed.

The second point I just want to make because I forgot to make it is that our survey data suggests that we are reaching the priority populations in much higher levels than others. So I know this is of keen importance to both of you, and our survey data bears out that they have higher receipt of the vaccine than others do, which I think is important to all of us.

Senator COLLINS. Thank you, Mr. Chairman.

Chairman LIEBERMAN. Thank you, Senator Collins. I appreciate that.

I want to ask you one take-away, Dr. Schukat, and, Senator Collins, I will understand if you got to vote before it gets too close to the end.

Senator COLLINS. Thank you.

Chairman LIEBERMAN. She has got a perfect record. I do not want to be the cause of creating a flaw there.

Am I right, from what I have heard previously and what you said in your opening statement, that you cannot as a scientist, or any of the others on the panel, predict what the course of the H1N1 virus is going to be from here on out?

Dr. SCHUCHAT. That is right, and we looked to the past, to other pandemics, to see what has happened. We do not know whether we will continue to have this high level of activity all the way through May, which is the usual end of flu season.

Chairman LIEBERMAN. And then coincide with the seasonal flu?

Dr. SCHUCHAT. Right. It could coincide with seasonal, but we looked very closely at 1957 where they had this fall increase like what we are having. It got a little better in December, and then

they had another big wave after the first of the year. People actually thought we do not need to bother vaccinating in December, and we do not want to make that mistake. So we do think we need to be ready for additional waves here in the United States.

Chairman LIEBERMAN. So the plan is, because of that unpredictability, although somewhat informed by experience, that the manufacturing facilities are going to continue to turn out the vaccine, and the country is going to continue to urge people, particularly in that 160 million at-risk population, to get the vaccine. Am I right?

Dr. SCHUCHAT. Yes, that is right, and we would imagine for the following year that if this strain is persisting, it might be rolled into the seasonal vaccine, a trivalent vaccine. For the winter—

Chairman LIEBERMAN. In other words, in the same shot.

Dr. SCHUCHAT [continuing]. And spring, we do feel like, ongoing efforts at prevention are going to be important.

Chairman LIEBERMAN. Well, I appreciate the testimony. I had a question for you, but since Senator Collins put you in the limelight and I have got to go vote, Dr. Garza. Obviously, the Secretary of Homeland Security is the incident manager here, and I know you staff her and support her in that role. I hope that you and she together will go back and look at this and try to draw some lessons from it so that some of the great things that have been done here do not for some reason end up causing the kind of frustration and anxiety that occurred this time around.

I appreciate that you looked back here in testimony today and acknowledged some things that you would do differently, and this is very important to the Committee not only because of the concern that influenza epidemics and pandemics will continue in the years ahead—you are right, we cannot expect to wait another 30 years—but also, of course, because of our homeland security responsibility to do our best to get the public health system up and ready to respond, God forbid, to, for instance, a biological terrorist attack, a bioterrorist attack. So, I thank you for all the hard work you have put in, for the testimony you have offered today, which is encouraging, and we look forward to seeing you again.

The record of the hearing will stay open for another 15 days for any additional statements or questions.

I thank you. The hearing is adjourned.

[Whereupon, at 4:47 p.m., the Committee was adjourned.]



# A P P E N D I X

**Prepared Statement of Senator Joseph I. Lieberman**  
**Homeland Security and Governmental Affairs Committee**  
**April 29, 2009**

Good morning and thanks very much to our witnesses for joining us today to discuss federal efforts to respond to the outbreak of swine flu here in the United States.

Both your agencies have critical roles to play in dealing with this situation. Under the Homeland Security Act, Homeland Security Presidential Directives 5 and 21, and the National Response Framework, the Secretary of Homeland Security serves as the overall incident manager and coordinates resources across the federal government in support of the response to the threat, while the Department of Health and Human Services, including CDC, leads the Federal public health and medical response.

The Centers for Disease Control and Prevention have confirmed 64 cases of the disease in the United States; Mexico has reported over 2,000 hospitalizations and 149 deaths; Canada has six confirmed cases. Spain and Scotland each have one confirmed case, while a handful of other countries have suspected cases.

Obviously, the people of Mexico are bearing the brunt of this crisis. Our thoughts and prayers are with them. President Felipe Calderon has taken strong precautions, closing schools nationwide, banning large public gatherings, ordering bars and restaurants closed, distributing face masks at subway and bus stations, and setting up medical units at airports to discourage sick people from traveling. I hope these measures will help to bring the epidemic in Mexico significantly under control.

But, this is a fast-moving disease with the potential for becoming a global pandemic. Outbreaks of infectious disease are unpredictable and variable, and circumstances of this outbreak have changed dramatically over the past several days. In addition to the toll on public health, the outbreak may have an impact on tourism and commerce. And we may well see the re-emergence of the swine flu next fall when the flu season begins again. It is essential, therefore, that we remain on heightened alert, take preventative action, and prepare for an escalation of the outbreak.

Madam Secretary, Rear Admiral Schuchat, (shook-it) I would say that, thus far, you have responded in a timely and efficient manner. The federal government, through CDC, DHS, the White House and other agencies, has tracked the spread of the disease, identified and addressed new cases in this country, and communicated its findings daily to the American people. Today, we will hear in greater detail about the actions our government is taking to manage this crisis.

So, our response to the swine flu outbreak has been reassuring. But we must ask if we are adequately prepared if this outbreak becomes a full-fledged pandemic?

Unlike other crises we have faced, pandemic flu is a threat that we have anticipated and begun to plan for. Nearly two decades ago, in 1992, the Institute of Medicine (IOM) reported that emerging microbial diseases are a serious threat, and that a number of modern demographic

and environmental factors increasingly favor their spread. We have since seen global outbreaks of Avian Bird Flu, West Nile Virus, SARS and a host of other infectious diseases - more than adequate confirmation that the IOM report was right.

In response, the CDC developed a national emerging infectious diseases strategy and President Clinton issued a presidential directive for federal agencies to begin a coordinated national response to the growing threat of infectious diseases.

In 2003, the nation experienced a particularly bad seasonal flu outbreak and flu vaccine shortages. I remember writing a letter to the Secretary of HHS at the time expressing concern over lack of resources and planning efforts for these types of occurrences.

Finally, in 2006, the Homeland Security Council published a National Strategy for Pandemic Influenza Implementation Plan, setting out a detailed roadmap for what to do in a crisis. States, supported by grants from DHS and HHS, have also developed plans for addressing pandemic flu. Today, I'd like to ask our witnesses how these plans have assisted with your response this past week.

Senator Collins and I are drafting legislation this Congress to implement key recommendations from the Graham-Talent WMD Commission report, which will include provisions strengthening the disbursement of counter measures during a pandemic or a biological attack – in other words, getting effective drugs quickly into the hands of those who need them.

Again, I would like to thank our witnesses for accommodating the Committee on short notice. We appreciate your efforts to work together to keep the public safe and well informed. Thank you. Senator Collins?

**Prepared Statement of Senator Susan M. Collins****Committee on Homeland Security and Governmental Affairs****April 29, 2009**

All of us are extremely concerned about the human swine flu outbreak that continues to grow in the United States and around the world. While the disease has so far been confined to six states, it is likely to spread further in the days to come. More than 150 people in Mexico are believed to have died from the virus, and just this morning the first death in the United States was confirmed by the CDC. There is also the dangerous potential that it will mutate into a more deadly strain or one that is even more infectious.

To date, it appears that our federal officials have taken this threat seriously and responded effectively. Today's hearing will give us the opportunity to learn more about what the federal government has done and what it plans to do to meet this growing public health threat.

On Sunday, the Department of Health and Human Services declared this incident a Public Health Emergency. This not only allows for the release of federal resources to support our preparedness and response efforts, but also gives agencies greater flexibility to put rapid measures in place should the swine flu virus become a more prevalent threat.

It also places the Secretary of Homeland Security in charge of the overall federal government's response. Consequently, DHS must work closely with HHS and its component agency, the Centers for Disease Control and Prevention, on the response. To hear about these coordinated efforts, I welcome Secretary Napolitano and Rear Admiral Anne Schuchat, from the CDC, here today.

Congress has provided authorities and funding to strengthen our nation's ability to respond to a pandemic incident, including the establishment of the Biomedical Advanced Research and Development Authority, or BARDA, at HHS. I strongly supported the creation of BARDA and increases to its funding.

To date, almost \$7 billion has been appropriated for federal pandemic preparedness activities. This funding has been used for stockpiling antiviral drugs for the treatment of more than 50 million Americans, licensing a pre-pandemic influenza vaccine, developing rapid diagnostics, and completing the sequencing of the entire genetic blueprints of 2,250 human and avian influenza viruses. And yesterday, President Obama asked for an additional \$1.5 billion to

combat this disease in the supplemental appropriation bill Congress will soon be considering.

Despite these authorities and funding, this Committee has uncovered weaknesses in pandemic flu planning and coordination. Last year, our Committee held a hearing on the mass medical care that would be needed in the response to a pandemic flu or the detonation of a terrorist's nuclear device. This hearing revealed serious gaps in this nation's capacity to provide mass care if thousands became ill.

The Committee also held a hearing on HHS's development and procurement of the necessary vaccines, drugs, and countermeasures for public health emergencies just like this one. In addition, we previously looked at the poor communications and coordination between DHS and the CDC in an incident involving a Mexican national with a multiple-drug-resistant form of Tuberculosis who was able to enter the U.S. twenty-one times after being identified by the CDC.

There are several important questions that we need to explore today. What has the federal government done so far to protect the American people from this potential pandemic? How are these plans working, and have we encountered any unanticipated problems? Since the Department of Homeland Security has put relatively passive inspection techniques in place at the border, should more be done to prevent cross-border contagion? What role should state and local health departments have in fighting this flu?

I particularly look forward to hearing about the status of the federal government's pandemic planning efforts. A critical part of this planning is the antivirals and other medical countermeasures from the Strategic National Stockpile that must be distributed rapidly to the public when needed. I would like to know whether we have enough of these and how they will be distributed.

As the previous hearing and this Committee's investigation about the Mexican national with TB highlighted, coordination between DHS and HHS is essential, as is communication with Mexican officials. I would also like to know how well DHS is coordinating its efforts with HHS, and how well they have communicated with Mexican authorities.

I am also concerned about how the lack of appointees in top positions at HHS and DHS may be hindering the effectiveness of the response. I'm sure that HHS has been handicapped by the absence of a Secretary and am pleased that the Senate voted last night to confirm Governor Sebelius' nomination. We still do not have a permanent head of the CDC, however, and DHS still does not have a Chief Medical Officer. This crisis requires effective leadership, and therefore, I look forward to hearing from Secretary Napolitano.

*Secretary*  
U.S. Department of Homeland Security  
Washington, DC 20528



**Homeland  
Security**

*Testimony of*  
*Janet Napolitano*  
*Secretary*  
*United States Department of Homeland Security*  
*before*  
*Senate Homeland Security and Governmental Affairs Committee*  
*April 29, 2009*  
*H1N1 Virus*

Chairman Lieberman, Senator Collins, and members of the committee: Thank you for this opportunity to testify about our national plan in response to the most recent outbreak of the 2009 H1N1 flu virus.

The flu outbreak that we are seeing in the United States is a serious situation that we are addressing aggressively. As President Obama has said, while this outbreak is not a cause for alarm, it is a cause for concern. As part of our precautionary measures, we are responding forcefully and preparing for further cases of the 2009 H1N1 flu virus though at this time we do not know the ultimate scope or severity of the outbreak. We expect this outbreak to develop over time – so our response will be a marathon, and not a sprint.

DHS' role in addressing the threat of this flu outbreak is clear: The Homeland Security Act instructs the Secretary of Homeland Security to lead the Department as a focal point for the federal government regarding crises and emergency planning. Under Homeland Security Presidential Directive 5 (HSPD-5), the Secretary of Homeland Security is the Principal Federal Official (PFO) for domestic incident management, which includes responding to large-scale medical emergencies. Under the National Response Framework, the Department of Health and Human Services (HHS) has the lead for public health and medical services, which include assessing public health and medical needs, conducting disease surveillance, providing public health and medical information, developing vaccines, and managing health, medical, and veterinary equipment and supplies. As part of HHS' response, HHS' Centers for Disease Control and Prevention (CDC) has responsibility for identifying and tracking the spread of the disease, conducting epidemiological investigations and laboratory tests, managing the Strategic National Stockpile (SNS) and providing SNS medicines and medical supplies to states,

and communicating health-related information to the government, the media, the public, and others. Within its role, DHS has taken a number of steps to protect the American public in concert with our interagency partners, with state, local, and tribal governments, and with the private sector.

Other federal departments play critical parts in our ongoing efforts. Through the Homeland Security Council, the President has made clear that this is an effort where everyone has a role to play. The Department of Education hosted a conference call earlier this week with more than 1,400 participants to guide education officials on how to identify, report, and prevent 2009 H1N1 flu in school facilities; the U.S. Department of Agriculture is reaching out to agriculture officials in every state to continue to affirm that no signs of this newly identified strain of H1N1 virus have been detected in our nation's swine, that no illnesses have been attributed to handling or consuming pork, and that there currently is no evidence that one can get the virus from eating pork or pork products; the Department of Defense continues to ready its plans to protect the men and women who serve our nation in the event that the outbreak escalates.

While I am speaking of partners, I cannot go without mentioning the strength and additional forces that our state, local, and tribal governments bring to this effort. DHS has initiated daily conference calls with our government partners. From our public health officials to the homeland security advisers of each state's governors, leaders are working around the clock to protect the safety of those they serve.

The public also plays a critical role in helping to prevent the spread of the this virus, so DHS and other responding agencies have been engaging with the public to communicate to Americans everything that is being done to protect against this flu

outbreak, and to educate people on steps they can take to protect themselves. We know that many Americans are concerned about this problem, and they deserve to be informed. I am pleased to be here with Rear Admiral Anne Schuchat, M.D. from the CDC, who will discuss her agency's role in our cooperative approach to mitigate the 2009 H1N1 flu outbreak.

I would also like to recognize Dr. Schuchat and the rest of the CDC for all the work they have done in the past weeks to combat this virus. Some have expressed concern about vacant political positions in the responding agencies, and while we will certainly welcome new appointees, this issue has not at all hindered the national response. We have benefited – and will continue to benefit – from the great work of career public health officials who have spent their careers in these fields, have prepared extensively, and have critical experience in dealing with what we are facing.

Currently, the United States has 50 million courses of anti-viral medication on hand that will have some efficacy against the 2009 H1N1 flu virus. Six million courses are dedicated for containment, and 44 million for treatment. Twenty-five percent (11 million courses) of the states' allotments of these stockpiled anti-virals, known commercially as Tamiflu and Relenza, are being released. Personal protection equipment is also being provided. While there is a priority placed on states that have confirmed cases of this flu, as well as on border states, all states have access to these extra resources. Resources are already being deployed to several states and we expect all of the 11 million courses will be deployed by May 3. These federal resources augment the roughly 23 million courses that states themselves have stockpiled. The CDC and the State

Department have also advised against non-essential travel to Mexico in order to mitigate the spread of 2009 H1N1 flu.

DHS has responded on numerous levels. Customs and Border Protection (CBP) is monitoring incoming travelers to identify individuals experiencing symptoms entering the U.S. and is providing information about the 2009 H1N1 flu virus to people who do decide to travel. We have also pre-positioned critical assets for our workforce in case the outbreak becomes more widespread and have conducted aggressive outreach to state and local authorities.

In our response, we are moving according to plans and protocols in the National Pandemic Strategy and Implementation Plan (PI) to effectively address an outbreak of this kind. We have taken action to get in front of this not just based on what's going on today, but on what could happen four months from now. We are prepared, and we are constantly evaluating the facts to ensure that we have a plan ready to be executed no matter how the threat evolves.

Indeed, this is a threat for which DHS and other levels of government have been preparing for a long time. While Governor of Arizona, I served as the co-chair of the National Governors Association panel on pandemic flu preparedness. I was able to see first-hand and help guide collaboration among states, DHS, HHS, and the CDC in preparing for potentially dangerous flu outbreaks. These preparedness exercises are now coming into great use, and the strong partnerships that formed as a result are now serving the American people well as we collaborate extensively across levels of government to mitigate this public health threat.

I would now like to explain a few of the actions DHS in particular has taken to mitigate the spread of this flu.

### **DHS Actions**

#### *Possibly Ill Travelers*

As infected travelers can lead to the spread of this virus, DHS is taking a number of precautions in light of the scope and nature of the threat.

At our land ports of entry and in our airports, CBP is continuing to implement protocols to direct incoming travelers who appear sick to separate rooms where they can be evaluated by local public health professionals. This is similar to the kind of monitoring that CBP conducts consistently, though obviously CBP is now in a heightened state of alert regarding 2009 H1N1 flu.

Furthermore, DHS is keeping travelers informed of the steps they should take to ensure their own health and the health of others in light of this outbreak. The Department is working with CDC to distribute "traveler's health alert notices" (THANs) issued by CDC to educate travelers. The notices explain 2009 H1N1 flu and its symptoms to the traveler and inform travelers of steps they should take in case they feel symptoms. CBP is issuing notices to those entering the country at land ports of entry, to aircraft passengers coming into the United States, and to passengers on cruise ships with destinations stops in Mexico. The Transportation Security Administration (TSA) is posting these notices at screening checkpoints and other airport locations.

Like the CBP, TSA has instituted protocols for passengers who may be exhibiting 2009 H1N1 flu symptoms to engage local health officials in order to evaluate their condition before further travel. Immigrations and Customs Enforcement (ICE) is also being vigilant and reviewing recent intakes in its detainee population to identify any detainees who might have contracted this flu. The Coast Guard is alerting health officials of any signs of this flu virus discovered on board commercial or private vessels while conducting routine Coast Guard duties, and is ensuring the shipping community is following established protocols for reporting ill crewmembers.

The actions we are taking regarding international travelers match the precautions advised by the CDC and the World Health Organization (WHO) based on the current, evolving epidemiology of the 2009 H1N1 flu virus. According to both the CDC and WHO, closing the border would yield only very marginal benefits; at the same time, closing the border has very high costs. The strain of the this virus that was first detected in Mexico is already present throughout the United States, and there is no realistic opportunity to contain the virus through border closures, so our focus must now be on mitigating the virus. The actions we are currently taking, as well as the travel advisories issued by the CDC and the State Department against non-essential travel to Mexico, should help to mitigate the number of people infected with 2009 H1N1 flu crossing the border.

*Outreach to State and Local Authorities, International Partners, and the Private Sector*

DHS is conducting extensive outreach to state, local and tribal partners so that they are fully apprised of all federal government actions regarding this flu outbreak, and to ensure that they are integrated in the response.

DHS' Office of Intergovernmental Programs (IGP) has instituted a daily conference call among all states – all top-level state and territorial homeland security advisors are invited to participate in these calls, which will continue as long as necessary. DHS is also actively working with cities that have been particularly affected, such as New York City. I have been in personal contact with the governors of virtually every state with a confirmed case of 2009 H1N1 flu, and I will continue to reach out to governors and states as the situation evolves.

FEMA is also prepared to respond as necessary to provide support, and is coordinating with affected states, HHS, the CDC and other partners to determine potential requirements.

In order to continue building a tri-national approach to addressing this virus, in the past few days, I have personally spoken with Arturo Sarukhan, the Mexican ambassador to the United States; my counterpart in Mexico, Interior Minister Fernando Gomez Mont; and my Canadian counterpart, Public Safety Minister Peter Van Loan. We recognize that viruses do not respect borders, and thus it is in our mutual interest to coordinate our efforts.

The Private Sector Office of DHS has reached out to its private-sector partners, in order to keep them informed of how DHS is addressing 2009 H1N1 FLU, and to communicate what they can do to mitigate the risk of this flu to their employees and the country. Efforts have focused in particular on reaching partners in the travel, aviation,

and hospitality industries. The DHS Office of Infrastructure Protection hosted a conference call with over 500 owners and operators of the Nation's Critical Infrastructure to keep them apprised of the situation as it develops.

#### *Preparing the Department*

The Department is taking many steps to ensure it continues to operate at full strength throughout the outbreak. As the leader of this Department, I know that if DHS is to protect the safety of our nation, we must ensure that we are doing all that we can to protect the safety of the DHS workforce. This effort has been a top priority for our leadership within the Department, especially working to keep safe our employees who are in the field with face-to-face public interaction everyday. To that end:

CBP has strategically positioned critical assets – including personal protection equipment (masks, sanitizers, etc.) and anti-viral drugs – in each of the nine Border Patrol sectors, in order to ensure that our agents at the border are protected against the virus to the maximum; similar actions have been taken by the U.S. Coast Guard in order to ensure our maritime borders continue to be guarded at full strength.

FEMA and U.S. Citizenship and Immigration Services are taking similar action to preposition critical supplies and protect their workforces and operations.

ICE is similarly prepared to meet the health and safety needs of its employees as well as those individuals in ICE custody. In preparing front-line employees that may be at risk, ICE has pre-positioned personal protective equipment for its law enforcement and mission-critical personnel not only at our borders and throughout the U.S.

Finally, the TSA is rapidly deploying personal protection equipment to 54 airports along the border and with flights from Mexico. The equipment includes masks, gloves, and hand sanitizer, in case those supplies are needed in a heightened state of precaution. DHS has been in contact with its employees about common-sense precautions they can take against 2009 H1N1 flu, in addition to information about the use of anti-viral drugs, should such a step become necessary.

### **Conclusion**

It is important that we continue to educate Americans about the 2009 H1N1 flu virus and the common-sense steps everyone can take to protect themselves, their families, and their neighbors. We urge Americans to take common flu-season precautions, such as washing hands, staying home from school or work if they feel ill, and covering mouths when coughing or sneezing. These are actions we can all take to guard against this flu.

Indeed, this is an effort that has a role for everyone: Our faith-based leaders can educate their congregations, community-based organizations can mobilize education campaigns in places from senior centers to daycare centers, and employers can communicate with their employees – not with a sense of fear, but with a sense of caution.

Obviously, our thoughts and prayers are with everyone in the United States and around the world affected by this virus. It is our job as a nation to work together to protect each other, and the federal government, states, and cities are acting in unison to do this every day.

Chairman Lieberman, Senator Collins, and members of the Committee: Thank you again for this opportunity to testify about the steps DHS is taking confronting this threat head-on and to secure America from this virus. I am now happy to take your questions.

	<p><b>Testimony before the Committee on Homeland Security and Governmental Affairs</b></p> <p><b>United States Senate</b></p>
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**U.S. Health Response to a Novel 2009  
H1N1 Influenza Virus**

***Anne Schuchat, M.D.***

**Acting Deputy Director for Science and Program,  
Centers for Disease Control and Prevention  
Assistant Surgeon General, U.S. Public Health Service  
*U.S. Department of Health and Human Services***

**For Release and Delivery  
Expected at 10:00am  
April 29, 2009**

Good morning, Chairman Lieberman, Ranking Member Collins and other distinguished members of the Committee. I am Dr. Anne Schuchat, Acting Deputy Director for Science and Program at the Centers for Disease Control and Prevention. I thank you for the opportunity to join Secretary Napolitano in updating you on current efforts the U.S. government is taking to respond to the ongoing novel 2009 H1N1 influenza outbreak. Our hearts go out to the people in the United States, in Mexico, and around the globe who have been directly impacted. People around the country and around the globe are concerned with this situation we're seeing, and we're concerned as well. We are responding aggressively at the federal, state, and local levels to understand the complexities of this outbreak and to implement control measures. It is important to note that our nation's current preparedness is a direct result of the investments and support of the Congress and the hard work of state and local officials across the country.

It is important for all of us to understand that flu viruses – and outbreaks of many infectious diseases -- are extremely unpredictable. We know that as our investigation proceeds, what we learn will change. We expect changes in the number of cases, the number of states affected, and the severity of illness. Our goal in our daily communication – to the public, to the Congress, and to the media – is to be clear in what we do know, explain uncertainty, and clearly communicate what we are doing to protect the health of Americans. An equal priority is to communicate the steps that Americans can take to protect their own health and that of their community. As we learn more, these communications and recommendations will evolve.

Influenza arises from a variety of sources; for example, swine influenza (H1N1) is a common respiratory disease of pigs caused by type A influenza viruses. These and other animal viruses

are different from seasonal human influenza A (H1N1) viruses. From laboratory analysis already performed at CDC, we have determined that there is a novel 2009 H1N1 virus circulating in the U.S. and Mexico that contains genetic pieces from four different virus sources. This particular genetic combination of H1N1 influenza virus is new and has not been recognized before in the United States or anywhere else worldwide. Additional testing is being done on the viruses, including a complete genetic sequencing.

CDC has determined that this virus is contagious and is spreading from human to human. It appears to spread with similar characteristics as seasonal influenza. Flu viruses are thought to spread mainly from person to person through coughing or sneezing of people with influenza. Sometimes people may become infected by touching something with flu viruses on it and then touching their mouth or nose. There is no evidence to suggest that this virus has been found in swine in the United States, and there have been no illnesses attributed to handling or consuming pork. Currently, there is no evidence that you can get this novel 2009 H1N1 influenza from eating pork or pork products. Of course, it is always important to cook pork to an internal temperature of 160 degrees Fahrenheit in order to ensure safety.

I want to reiterate that as we look for cases, we are seeing more cases. We fully expect to see not only more cases, but also greater severity of illness. We've ramped up our surveillance around the country to try and get a better understanding of the magnitude of this outbreak.

Let me provide for you an update in terms of the public health actions that are being taken here as well as abroad. On the investigation side, we are working very closely with state and local

public health officials around the country. We're providing both technical support on the epidemiology as well as laboratory support for confirming cases. We are also working with the World Health Organization, the Pan American Health Organization, and the governments of Mexico and Canada on this outbreak. There is a tri-national team that is working in Mexico to better understand the outbreak, and answer critical questions such as why cases in Mexico appear to be more severe than we have seen in the U.S. to date. We are working to assist Mexico in establishing more laboratory capacity in-country; this is very important because when you can define someone as a truly confirmed case, what you understand about how they acquire disease takes on much more meaning.

In terms of travel advisories, CDC continues to evaluate incoming information from the World Health Organization, the Pan American Health Organization, and other governments to determine the potential impact of the outbreak on international travel. On Monday, April 27<sup>th</sup>, CDC issued a travel health warning for Mexico. With this warning, we recommend travelers to postpone non-essential travel to Mexico for the time being. CDC is also evaluating information from other countries and will update travel notices for other affected countries as necessary. As always, persons with flu or flu-like symptoms should stay at home and should not attempt to travel.

CDC has and will continue to develop specific recommendations for what individuals, communities, clinicians, and others professionals can do. It is important that people understand that there's a role for everyone to play when an outbreak is occurring. At the individual level, it is important for people to understand how they can prevent respiratory infections. Very frequent

hand-washing is something that we talk about time and time again and that is an effective way to reduce transmission of disease. If you're sick, it's very important to stay at home. If your children are sick, have a fever and flu-like illness, they shouldn't go to school. And if you're ill, you shouldn't get on an airplane or any public transport to travel. Taking personal responsibility for these things will help reduce the spread of this new virus as well as other respiratory illnesses.

It is important that people think about what they would do if this outbreak deepens in their community. Communities, businesses, schools, and local governments should plan now for what to do if cases appear in their communities. Parents should prepare for what they would do if faced with temporary school closures, as we are recommending temporary school closures when cases are identified.

We also have additional community guidance so that clinicians, laboratorians, and other public health officials will know what to do should they see cases in their community. All of these specific recommendations, as well as other regular updates, are posted on the CDC web site – [www.cdc.gov](http://www.cdc.gov).

We will continue to provide support to states and communities throughout this outbreak. In addition to the epidemiologic and laboratory support that CDC provides, CDC maintains the nation's Strategic National Stockpile of medications that may be needed in this outbreak. As part of our pandemic preparedness efforts, the U.S. Government has purchased extensive

supplies of antiviral drugs -- oseltamivir and zanamivir -- for the Strategic National Stockpile. Laboratory testing on the viruses so far indicate that they are susceptible to oseltamivir and zanamivir. We are releasing one-quarter of the states' share of antiviral drugs and personal protective equipment to help states prepare to respond to the outbreak, along with the necessary emergency use authorities to facilitate their effective use. Distribution has been prioritized for the states where we already have confirmed cases. In addition, the Department of Defense has procured and strategically prepositioned 7 million treatment courses of oseltamivir.

Whenever we see a novel strain of influenza, we begin our work in the event that a vaccine needs to be manufactured. The CDC is working to develop a vaccine seed strain specific to these viruses -- the first step in vaccine manufacturing. This is something we often initiate when we encounter a new influenza virus that has the potential to cause significant human illness. We have isolated and identified the virus and discussions are underway so that should we need to manufacture a vaccine, we can work towards that goal very quickly. HHS has also identified the needed pathways to provide rapid production of vaccine after the appropriate seed strain has been provided to manufacturers. As this progresses, HHS operating divisions and offices including CDC, NIH, FDA, and ASPR/BARDA will work in close partnership.

In closing, we are simultaneously working hard to understand and control this outbreak while also keeping the public and the Congress fully informed on the situation and our response. We are working in close collaboration with our federal partners including our sister HHS agencies and other federal departments. While much has happened to date, this will be a marathon, not a sprint, and even if this outbreak is a small one, we can anticipate that we may have a subsequent

or follow-on outbreak several months later. Steps we are taking now are putting us in a strong position to respond.

The government cannot solve this alone, and as I have noted, all of us must take constructive steps. If you are sick, stay home. If children are sick, keep them home from school. Wash your hands. Take all of those reasonable measures that will help us mitigate how many people actually get sick in our country.

Finally, it is important to recognize that there have been enormous efforts in the U.S. and abroad to prepare for this kind of an outbreak and a pandemic. The Congress has provided strong support for these efforts. Our detection of this strain in the United States came as a result of that investment and our enhanced surveillance and laboratory capacity are critical to understanding and mitigating this threat. While we must remain vigilant throughout this and subsequent outbreaks, it is important to note that at no time in our nation's history have we been more prepared to face this kind of challenge. As we face the challenges in the weeks ahead, we look forward to working closely with the Committee to best address this evolving situation.

<b>Question#:</b>	1
<b>Topic:</b>	plans
<b>Hearing:</b>	Swine Flu: Coordinating the Federal Response
<b>Primary:</b>	The Honorable Joseph I. Lieberman
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Questions and Answers for the Record  
Submitted by Janet Napolitano, Secretary,  
U.S. Department of Homeland Security**

**Question:** In your written testimony to the Committee, you indicated that DHS was “moving according to plans and protocols in the National Pandemic Strategy and Implementation Plan to address the H1N1 outbreak.”

Has DHS, or any of the Department’s offices components, developed its own plans and protocols for addressing a potential flu pandemic?

**Response:**

<b>Pandemic Plans and Protocols</b>	<b>Type</b>	<b>Status</b>	<b>Developed by</b>
DHS Pandemic Influenza Contingency Plan (OCT 06)	Operational	Final Draft, Never approved	DHS (NPPD)
Federal Pandemic Influenza Concept Plan (CONPLAN) (DEC 07)	Operational	Final Draft	DHS (IMPT/OHA)
Federal Pandemic Influenza Playbook (OCT 07)	Operational	Final Draft	DHS (IMPT/OHA)
Federal Pandemic Influenza Smartbook (OCT 07)	Operational	Final Draft	DHS (IMPT/OHA)
Federal Pandemic Influenza Border Management Plan (DEC 07)	Operational	Final Draft	DHS (IMPT/OHA)

<b>Question#:</b>	1
<b>Topic:</b>	plans
<b>Hearing:</b>	Swine Flu: Coordinating the Federal Response
<b>Primary:</b>	The Honorable Joseph I. Lieberman
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:**

Please list, and provide to the Committee a copy of, all written plans or protocols (including any draft plan) whether strategic, operational or otherwise to address pandemic flu that have been developed by DHS or any office or component of DHS, or which were relied on by DHS or any of its offices or components in the response to the recent outbreak of H1N1.

**Response:**

DHS leverages all previous pandemic influenza planning products to develop a series of strategic and operational plans to respond to the H1N1 outbreak in the United States. For example, the HSC published the Pandemic Checklist which, was based on the previous Federal Pandemic Influenza CONPLAN. As a follow up to this checklist, DHS is developing the *Federal H1N1 Flu Strategic Implementation Plan (I-Plan)* to be released in the near future. Furthermore, DHS is also drafting a Department H1N1 Flu Implementation Plan (I-Plan) which is currently undergoing an intra-Departmental review.

In January of 2007, the U.S. Immigration and Customs Enforcement (ICE) Respiratory Protection Program Policy was approved. The policy ensures that ICE employees are protected from exposure to respiratory hazards, such as pandemic influenza, in the performance of their official duties. In March of 2007, the ICE Pandemic Influenza Contingency Plan was approved, establishing comprehensive protocol to address the threat of a pandemic influenza on ICE operations and our nation. The ICE Plan was created for ICE program and field offices and stakeholders. The ICE Plan addresses specific actions that ICE can take in support of the public health response to a pandemic, as well as defining activities required to remain true to ICE's primary mission. The H1N1 OPT under OHA and OPS has engaged an interagency working group to develop a multi-incident plan under H1N1 conditions. To date, the working group has prepared an information analysis briefing and has developed 4 courses of action centered on Federal Coordination Team (FCT) activation and deployment and strategies to coordinate a multi-incident event.

<b>Question#:</b>	2
<b>Topic:</b>	screening
<b>Hearing:</b>	Swine Flu: Coordinating the Federal Response
<b>Primary:</b>	The Honorable Joseph I. Lieberman
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:** In your written testimony, you characterized the current posture at the ports of entry as one of passive screening, and noted that “right now we don't think the facts warrant a more active testing or screening of passengers coming in from Mexico.” You noted that air carriers and CBP employees at the airports check to see if people are sick, and encouraging them not to board the plane if they are in fact sick.

Please describe in more detail what this passive response entails. Do you believe that the facts on the ground still justify a passive response at the ports of entry? What would trigger an active screening response?

**Response:**

CBP Officers look for signs of illness when processing passengers and crewmembers arriving to the United States. The suspected ill travelers exhibiting signs of disease and arriving from affected countries are detained by CBP and referred for CDC disposition.

- **Watching for Illness:**

The recognition and reporting of overt visible signs of illness, provided in the course of routine interactions with detainees, passengers or crewmembers. “Watching for illness” does not involve a medical examination or obtaining a medical history.

- **Active Surveillance:**

At the CDC's request and as specifically directed by CBP Headquarters, CBP Officers and Agriculture Specialists may assist in performing active surveillance. Active surveillance is to identify ill persons suspected of possible infection with, or exposure to, pandemic influenza. Active measures are risk-based, can be varied, and will depend upon the location and extent of the pandemic outbreak. It may consist of a number of CDC-approved and imposed methods to assess risk that people entering the United States from affected countries or regions are carrying a quarantinable disease. These measures may be implemented at heightened time of operations during a declared pandemic.

**Question:**

<b>Question#:</b>	2
<b>Topic:</b>	screening
<b>Hearing:</b>	Swine Flu: Coordinating the Federal Response
<b>Primary:</b>	The Honorable Joseph I. Lieberman
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

Under what circumstances would CBP not allow somebody to enter the country, or bar someone from boarding an airplane to leave the country?

**Response:**

CBP Officers will assist quarantine officers, other CDC personnel or CDC designees, with the enforcement of quarantine rules and regulations imposed upon those passengers or crewmembers designated by CDC to be subject to a temporary detention, isolation, surveillance or quarantine order issued by CDC.

For an alien to be found inadmissible under the health related grounds of INA § 212(a)(1)(A)(i) it must be in accordance with regulations prescribed by the Secretary of Health and Human Services. Inadmissibility under § 212(a)(1)(A)(i) of the INA cannot be determined by a CBP Officer. Section 232(b) of the INA in part states "...The physical and mental examination of arriving aliens...shall be made by medical officers of the United States Public Health Service, who shall conduct all medical examinations and shall certify, for the information of the immigration officers and the immigration judges, any physical and mental defect or disease observed by such medical officers in any such alien."

A panel physician (visa processing), public health service officer, or designated civil surgeon (designated by CIS in the United States) must issue a Class A medical certification for an alien to be found inadmissible under INA section 212(a)(1). INA § 232 makes very clear that the medical examination is done by PHS officers (or civil surgeons – or, in the consular context, panel physicians).

Although a CBP officer may suspect that an alien may be inadmissible under 212(a)(1), the CBP officer cannot find the alien inadmissible without the Class A medical certification.

If the panel physician, PHS officer, or civil surgeon issues the Class A certification, the alien is inadmissible, unless such condition is waived pursuant to INA § 212(g).

Thus, if the panel physician, PHS officer, or civil surgeon does not issue the Class A certification, the alien is not inadmissible on account of health-related grounds under § 212(a)(1).

<b>Question#:</b>	2
<b>Topic:</b>	screening
<b>Hearing:</b>	Swine Flu: Coordinating the Federal Response
<b>Primary:</b>	The Honorable Joseph I. Lieberman
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:**

Would a U.S. Citizen ever be denied entry for public health concerns? What kind of procedures are in place to handle infected U.S. citizens returning from abroad during a pandemic flu?

**Response:**

US Citizens who are exhibiting symptoms of a communicable or quarantinable disease will be admitted, but are referred to CDC and subject to a CDC medical determination, and any conditions CDC may place on them (e.g., self-isolation, quarantine, etc) pursuant to the exercise of their authorities.

CDC maintains jurisdiction over the execution of detention, isolation, quarantine, and surveillance orders, which CBP personnel may be called upon to help enforce.

CBP provides assistance to HHS/CDC, at their request, by detaining specific individuals encountered at the U.S. border who may be infected with a communicable or quarantinable disease. In such cases, CBP may assist with the enforcement of an order or instruction provided by HHS/CDC. If, during normal CBP processing of travelers, a CBP officer ascertains that an individual exhibiting signs and/or symptoms of a potentially serious communicable or quarantinable disease is a US Citizen or a Lawful Permanent Resident and there is no other basis to detain or arrest the individual, CBP will request the consent of the individual to remain on site while personnel coordinate with the CDC or other appropriate health authorities. In such circumstances, any CBP detention or action will be governed by the scope of consent provided by the specific individual.

Once consent has terminated, unless CDC has provided a written request to detain (for example, in the form of a detention, isolation, quarantine, or surveillance order that is faxed or forwarded to CBP), CBP would permit the individual to leave the area, as long as all other inspectional duties or responsibilities have been met.

**Question:**

What training has been provided to CBP officers at the ports of entry to identify potential cases of H1N1 infected travelers?

**Response:**

<b>Question#:</b>	2
<b>Topic:</b>	screening
<b>Hearing:</b>	Swine Flu: Coordinating the Federal Response
<b>Primary:</b>	The Honorable Joseph I. Lieberman
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

In addition to information in musters, the daily meeting with CBP Officers and management (usually just prior to the start of a shift) to provide situational awareness, and memos that are routinely provided to CBP Officers to assist them with the identification of potential cases of H1N1, the following courses related to Pandemic Events provide required training for CBP Officers and are available through the CBP Virtual Learning Center or are provided at the basic academy.

**Public Health and the CBP Role** – The Centers for Disease Control and Prevention present a two hour blocked course for U.S. Customs and Border Protection Officers and Agriculture Specialists, which is taught by a CDC Quarantine Officer.

**Avian Influenza Awareness Program** – Introductory module of Avian Influenza Awareness that prepares employees for a potential pandemic event.

**Pandemic Influenza Safety** – Employee safety module relative to pandemic influenza designed to reduce risk of employee exposure, contamination and spread of the disease. Instruction includes information on personal protective equipment and protective measures during all levels of progression.

**Pandemic Influenza Safety – Protecting Your Family**—Employee safety module relative to pandemic influenza and reducing the risk of exposure, contamination and spread of the disease.

**Pandemic Influenza Safety – Protecting the Public**- Safety training relative to pandemic influenza to reduce the risk of exposure, contamination and spread of the disease in employee interactions with the public.

**CBP Pandemic Preparedness and Response** – CBP preparedness and response course for continuity of operations during the phases of a pandemic event.

<b>Question#:</b>	3
<b>Topic:</b>	protective guidance
<b>Hearing:</b>	Swine Flu: Coordinating the Federal Response
<b>Primary:</b>	The Honorable Joseph I. Lieberman
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:** As our first line of defense against incoming biological threats, CBP officers at the ports of entry inevitably assume some risk of infection as they interview the millions of people who present themselves for entry into the United States each year.

Has protective guidance has been issued to DHS employees, including CBP officers at the ports, border patrol agents, and TSA screeners, regarding the H1N1 flu and other biological threats? Has there been, or do you anticipate that there will be, government-wide guidance issued to federal employees on protective measures against such threats? Please provide the Committee with copies of any such guidance which has been issued to DHS employees.

What protective equipment has been distributed to the ports of entry to ensure that CBP officers and other DHS employees are not exposed to any excess risks as they screen passengers? How and when would those assets be distributed?

**Response:**

Yes, initial guidance was issued to all DHS employees by the Under Secretary for Management on April 30, 2009. On May, 29, 2009, DHS revised its policy regarding the use of Personal Protective Equipment (PPE) in accordance with a Centers for Disease Control (CDC) update. Per the new guidance, the Department permits employees whose work requires them to come into close contact (less than 6 feet) with persons who may have the flu or are exhibiting flu-like symptoms to wear facemasks or N95 respirators and follow other CDC recommendations to lessen the spread of the H1N1 flu. DHS has provided PPE to its employees, including facemasks, respirators (N95), and gloves, and DHS continues to provide PPE to all DHS employees. In addition, DHS has provided hand sanitizer gel to its employees.

DHS is also working closely with OSHA to develop a broad spectrum of protective measures for DHS employees who may be occupationally exposed to persons with H1N1, including engineering controls (permanent measures that will prevent close contact) and administrative controls that will provide protection superior to total reliance on respirators for DHS employees.

The guidance to employees and the memo from the Under Secretary for Management to Component heads are attached.

<b>Question#:</b>	4
<b>Topic:</b>	diagnostic tool
<b>Hearing:</b>	Swine Flu: Coordinating the Federal Response
<b>Primary:</b>	The Honorable Susan M. Collins
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:** Over the past decade, Congress has allocated significant funding to DHS and CDC to address a potential pandemic, but no point-of-care diagnostic tool is being utilized for this outbreak as funding has been spent primarily on vaccines. An effective diagnostic tool could be useful in containing an outbreak if it can quickly identify those with the virus whether at the border or in spotting the worried well filling emergency rooms during an outbreak. Do you believe that this is a gap in our preparedness for spotting a potential epidemic and preventing a pandemic?

**Response:** The ability to quickly identify a contagious virus can potentially reduce the level of infected persons by rapidly identifying those who are ill, thereby making it possible to provide early treatment and to separate those who are ill from healthy individuals. The Department of Homeland Security (DHS) is tasked with coordinating preparedness and response activities during events that threaten National security. While we collaborate on a number of health related activities with our interagency partners, especially the Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC), DHS is not responsible for development of new medical technologies and medical countermeasures. HHS/CDC is working on development of number of diagnostic tools that would be beneficial in rapidly identifying sick people. We recommend the Committee consult with HHS/CDC on the specifics of their programs.

<b>Question#:</b>	5
<b>Topic:</b>	CMO
<b>Hearing:</b>	Swine Flu: Coordinating the Federal Response
<b>Primary:</b>	The Honorable Susan M. Collins
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:** In implementing PKEMRA's reforms, Secretary Chertoff further expanded the duties of the CMO and established the CMO as the head of an Office of Health Affairs. Since its establishment in 2005, the CMO/Office of Health Affairs has grown dramatically and has played a central role in other medical emergencies, such as those involving extremely drug resistant TB. Given the importance of the CMO to Congress, please explain the role played by the Office of Health Affairs/CMO during this current emergency.

**Response:** In July 2008, former Department of Homeland Security (DHS) Secretary Chertoff delegated the Office of Health Affairs (OHA) with the authority to exercise oversight over all medical and public health activities of DHS. OHA has provided medical expertise to numerous health incidents including the XDR-TB incident you mentioned. The office maintains the ability to access physicians on short notice to discuss emergent health issues at the request of Department leadership. Since the TB case referenced, OHA has also become involved in the maintenance of the "Do Not Board List" based on travelers' symptoms.

OHA staff was involved in the earliest discussions to take place, discussions that occurred when the initial H1N1 influenza cases with a connection to the deaths in Mexico were first reported in the United States. OHA implemented an Incident Management Cell (IMC), now referred to as the Decision Support Cell (DSC), to support the National Operations Center (NOC) and to provide the CMO with critical up to date information to guide him in his decision making and advice to the Secretary and to coordinate responses to inquiries. Requests for information and action came from the Secretary, DHS offices and components, Federal partners, the White House, State and local officials, and private citizens. All of these activities are coordinated through the NOC. The DSC continues to be operational at a lower level of activity and will do so until it is determined that the outbreak is over.

In addition to operating the DSC, OHA worked closely with Federal partners to obtain accurate and complete awareness of emerging cases of individuals infected with H1N1. Staff acquired up to the minute lists of H1N1 cases from a variety of sources such as the Centers for Disease Control and Prevention (CDC), the World Health Organization (WHO) and intelligence sources. This information also includes the source country or State of the infected individual. In cooperation with the Management Directorate, OHA prepared guidance for Departmental employees to protect them against infection based on the best science available. OHA staff worked with the US Fire Administration, the

<b>Question#:</b>	5
<b>Topic:</b>	CMO
<b>Hearing:</b>	Swine Flu: Coordinating the Federal Response
<b>Primary:</b>	The Honorable Susan M. Collins
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

National Highway Traffic Safety Administration, Office of Emergency Medical Services (EMS), the National EMS Managers Association, the National Association of State EMS Officials, and other Federal partners (HHS/CDC) to draft and release EMS and 9-1-1 Guidance to first responders. Staff also developed guidance for the private sector and the law enforcement communities. The Food, Agriculture, and Veterinary Defense division within OHA worked closely with partners at the United States Department of Agriculture (USDA) to monitor cases of infected swine and avian species. BioWatch laboratories in the Laboratory Response Network (LRN) provided surge support and analyzed samples to detect H1N1 infection. The National Biosurveillance Integration Center (NBIC) analyzed and provided consolidated information updates to senior level decision-makers in the form of Daily Situational Reports on the H1N1 incident.

OHA provided valuable medical expertise during the H1N1 response. In late May, OHA performed an after-action analysis of its response and operations during the initial H1N1 outbreak. Staff will continue to work with our DHS and Federal partners to address any issue(s) identified during this process to ensure an enhanced response during future outbreaks.



# Homeland Security

May 29, 2009

MEMORANDUM FOR: Component Heads

FROM: Elaine C. Duke   
Under Secretary for Management

SUBJECT: DHS Policy Guidance on Personal Protective Equipment (PPE)

The Centers for Disease Control and Prevention (CDC) has issued new interim recommendations for mask and respirator use for home, community, and occupational settings to prevent the spread of H1N1 flu. The revised CDC guidance does not recommend mandatory use by employees in DHS' occupational setting, even in the high-risk category of exposure. The new guidance changes the recommended protocols for workers in the high-risk category and clarifies the protocols for workers in the non high-risk category.

As a result of this new guidance:

- The Under Secretary for Management policy issued April 30, 2009, regarding mandatory use of masks for DHS employees in the high risk category for exposure to novel H1N1-infected persons is replaced by this guidance.
- DHS permits employees whose work requires them to come into close contact (less than 6 feet) with persons who may have the flu or are exhibiting flu-like symptoms to wear facemasks or N95 respirators and follow other CDC recommendations to lessen the spread of the H1N1 flu. DHS will provide Personal Protection Equipment (PPE) to its employees, including facemasks and respirators.
- DHS will continue to follow existing Occupational Safety and Health Administration (OSHA) requirements for voluntary use of respiratory protection. Facemasks or respirators may be used when work activities require close contact with a person with influenza-like symptoms (fever plus a cough or sore throat). Such activities may include escorting, interviewing or providing assistance to individual with such symptoms. In these situations, CDC recommends that employees interacting with individuals exhibiting influenza-like symptoms should:
  - Maintain a distance of six feet or more;
  - Keep their interactions as brief as possible;
  - Ask individuals with symptoms to wear a facemask, if able, and one is available;
  - Avoid individuals with symptoms if there is an increased risk of severe illness from influenza (through temporary reassignment); and,
  - Should consider wearing a facemask or respirator on a voluntary basis if contact cannot be avoided.

Our goal is to ensure that employees have access to the most current information available. We will continue to keep you apprised of any updates released by the CDC. Further information and protective measures on H1N1 flu can be found at [www.cdc.gov/h1n1flu/guidance/](http://www.cdc.gov/h1n1flu/guidance/)

**Bertucci, Nicole M**

**From:** DHS Employee Communications  
**Sent:** Thursday, April 30, 2009 8:29 PM  
**To:** ^DHS-HQ-ALL-QB  
**Subject:** MESSAGE FROM ELAINE DUKE, UNDER SECRETARY FOR MANAGEMENT: INTERIM GUIDANCE ON PERSONAL PROTECTIVE EQUIPMENT (PPE)



**Homeland  
Security**

**April 30, 2009**

**TO:** All DHS employees  
**FROM:** Elaine Duke, Under Secretary for Management  
**RE:** Interim Guidance on Personal Protective Equipment (PPE)

Because many of our employees work in the field where they may come in contact with people who have contracted the 2009 H1N1 flu virus, this guidance is being released as an interim measure until the Office of Personnel Management provides comprehensive guidance for all federal employees.

This guidance is based on DHS' work with the Department of Labor's Occupational Safety and Health Administration (OSHA) and the Centers for Disease Control and Prevention (CDC). This guidance will be augmented as necessary and we will continue to keep employees apprised of any new guidance that may be issued.

For all employees, taking protective measures is critically important, no matter what tasks they are performing.

All employees should:

- Wash hands frequently with soap or sanitizing solutions
- Cover their mouths when they cough
- Stay home from work if feeling ill

In addition, the following employees **MUST** wear Personal Protective Equipment.

- Employees who work closely with (either in contact with or within 6 feet of) people specifically known or suspected to be infected with the H1N1 virus must wear respiratory protection.
  - For example: CBP, TSA, and ICE employees who are in close proximity to a person who is being held in isolation due to flu-like symptoms must wear a mask.

A mask with an N95 or higher-rated filter is required for these situations.

Employees who have underlying conditions – such as pregnancy, asthma, or cardiac or kidney disease – and cannot wear a mask should consult with their component Safety and Health Officers and Supervisors for alternative risk reduction measures.

Employees may request further information and guidance from DHS Office of Health Affairs and DHS Office of Safety and Environmental Programs.

Further information and protective measures on H1N1 flu can be found at [www.cdc.gov](http://www.cdc.gov).

**Post-Hearing Questions for the Record  
Submitted to Rear Admiral Anne Schuchat, M.D.  
From Senator Joseph Lieberman**

**“Swine Flu: Coordinating the Federal Response”  
April 29, 2009**

- 1. The CDC has reported that it has already started to create the seed stocks for developing a vaccine against swine flu. However, the federal government has not yet made the decision to actually ask manufacturers to commit to full production of an H1N1 vaccine.**

**1a. If the federal government decides to pursue an H1N1 vaccine, how long will it take to start producing a new vaccine?**

**Response:** The process of developing an H1N1 influenza vaccine for large-scale production later this year is progressing steadily. In early June, CDC shipped candidate virus seed strains to U.S.-licensed manufacturers of influenza vaccine. Manufacturers started the process of developing a vaccine by producing candidate lots during June and July for use in clinical studies, which will begin in August. The FDA, BARDA, and NIH are coordinating with the manufacturers to complete these preparations. Manufacturers located outside the U.S. are preparing for clinical testing in other countries around the world as well. Clinical studies will determine the appropriate dosage for eliciting an effective immune response, the number of injections needed, implications for different age groups, and whether an adjuvant is needed to produce an acceptable response or to achieve a realistic dosage. The results of these trials will be available in late September-early October. While clinical testing is underway to determine the optimal vaccine formulation, manufacturers will proceed to produce bulk antigens and bulk adjuvant per contracts awarded by BARDA. A decision to fill and finish a vaccine for a U.S. immunization campaign probably would be made in late summer or early fall. This decision will be informed by results of current surveillance of novel H1N1 cases in the Southern Hemisphere, and based on the predicted impact of the virus on the U.S. during the coming winter flu season. If the decision is made to go forward, the vaccine formulation (or formulations for different population and age groups) determined from clinical testing will then be produced from the bulk components already manufactured. An estimate of the time at which this will occur depends on how each of the steps above proceed, but will probably allow first vaccine doses to be available in the Fall.

**1b. If the federal government decides to pursue an H1N1 vaccine, how long will it be before we can reasonably expect have produced and distributed sufficient vaccine quantities to be able to vaccinate 300 million Americans?**

**Response:** First doses of vaccine will likely be available by mid-October to early November, assuming the development and manufacturing processes go smoothly. Vaccine then will continue to be produced and delivered until sufficient vaccine has been produced to immunize all target

U.S. populations. The timing by which this will occur depends on a number of variables whose values cannot yet be determined: the amount of adjuvant required per dose; the number of doses required per person; whether adjuvant is included (and its impact on dosage and number of doses); and the manufacturing yield of the bulk antigen. In almost any scenario, producing and delivering vaccine for 300 million people will take several months or more. For this reason, it is likely that any immunization plan will be prioritized, starting with critical workforce and proceeding with high risk groups determined by clinical results, then finishing with the remainder of the population. All factors that allow a program to be implemented that produces the greatest public health benefit, and protects all Americans as quickly as possible, will be taken into consideration. One key consideration may be the use of adjuvanted vaccine formulations, in some or all populations, to reduce the antigen dosage and/or number of doses required, and thus extend the number of people that can be immunized with the available amount of antigen. This option is discussed further in the following response.

**1c. During your testimony you mentioned that consideration is being given to the use of adjuvants in the formulation of a possible H1N1 vaccine. Would the use of adjuvants allow us to provide vaccine to more people in a faster manner than if we decide not to use an adjuvant? If so, which types of adjuvant are being considered?**

**Response:** As noted in the preceding response, adjuvanted vaccine formulations may be key to an immunization program that allows all Americans to be protected in a timely manner during the coming flu season. Substantial data has been generated with other (avian H5) influenza vaccines showing that certain adjuvants can significantly reduce, by a factor of up to 4-16, the amount of antigen required to elicit a protective response. If H1N1 trials show a similar effect, the use of adjuvants could therefore extend the available antigen supply, and reduce the time to immunize the U.S. population, by a similar factor. This could make the difference between an immunization program that leaves many Americans unprotected during the coming flu season and one that covers most, if not all, Americans in this critical timeframe. The data needed to evaluate and choose the optimal scenarios will be obtained in the clinical trials now beginning. Two adjuvants that have extensive development history with influenza vaccines, and that are already proceeding through the FDA regulatory process are currently under consideration for use in H1N1 vaccine; GlaxoSmithKline's AS03 and Novartis' MF59. Neither of these adjuvants is currently licensed for use in the United States (although they are licensed elsewhere and in other vaccines), so use of adjuvanted vaccine formulations will require authorization under emergency use regulatory provisions if supported by data suitable safety and efficacy.

**1d. What is the domestic capacity to manufacture influenza vaccine annually?**

**Response:** Recent U.S. domestic production capacity for annual seasonal influenza vaccines is approximately 135 - 140 million doses, based on the 2007/08 and 2008/09 influenza seasons.

**Influenza Vaccine Production and Distribution for 2000/01 – 2008/09 Seasons**

<b>Influenza Season</b>	<b>Doses Produced (in millions)</b>	<b>Doses Distributed in Millions (%)<sup>1</sup></b>
2000-2001	77.9	70.4 (90%)
2001-2002	87.7	77.7 (89%)
2002-2003	95.0	83.0 (87%)
2003-2004	86.9	83.1 (96%)
2004-2005	61.0	57.0 (93%)
2005-2006	88.1	81.1 (92%)
2006-2007	115.0	102.5 (89%)
2007-2008	140.6	112.8 (80%)
2008-2009	135.9	113.0 (83%)
2009-2010 <sup>2</sup>	TBD	TBD

<sup>1</sup>Data provided by vaccine manufacturers. CDC does not have data on the number of influenza vaccine doses administered or not used each year.

<sup>2</sup> The production estimate for the 2009-2010 influenza season is not known at this time. More information about production estimates for seasonal influenza vaccine should be available after August 2009.

**1e. Are we able to simultaneously prepare both the seasonal flu and the H1N1 flu vaccines if we decide that we need both available this fall?**

**Response:** The manufacturing process for seasonal influenza vaccine for the US (i.e. Northern Hemisphere) is well on its way to completion. The emergence of novel H1N1 disease during spring in the United States has given us an opportunity to work with manufacturers on monovalent vaccine development. Had the novel H1N1 virus emerged during the fall, we would not have had this flexibility. [Source: May 28 press briefing, Dr. Schuchat – transcript on CDC Web site, <http://www.cdc.gov/media/transcripts/2009/t090528.htm> (accessed 6.5.09) - CES]

- 2. During the response to the H1N1 outbreak, the CDC released 25%, or 11 million courses, of the 44 million courses of the anti-viral treatments Tamiflu and Relenza from the Strategic National Stockpile in a timely manner to all 50 states. However, in the event of a pandemic with a profile similar to that of the 1918 pandemic, we will not only need to get anti-virals and vaccines to State warehouses, but actually into people's hands.**

**2a. Are we prepared today as a nation to administer these millions of doses of antiviral medications and vaccinations if we were to face a pandemic level affecting tens of millions people?**

**Response:** The federal influenza response strategy calls for stockpiling enough antiviral drugs to treat up to 25 percent of our nation's population who may become infected with a pandemic

influenza virus. This target is being met through a combined effort of states' participation in the federally subsidized program to purchase antiviral drugs for their state-maintained stockpiles with a targeted goal of 31 million regimens, in addition to the 50 million regimens maintained by the SNS (*Note: As of May 2009 23 million regimens of the targeted 31 million had been purchased by states under the subsidy program. Additionally, 13 million antiviral drug regimens are currently on order to replenish SNS quantities back to the pre-H1N1 total of 50 million regimens; receipt of these orders is anticipated to occur by September 2009.*)

Once states receive these assets it is their responsibility to further distribute them to medical facilities (hospitals, clinics, and alternate care facilities) where they will then be dispensed for the purpose of treating symptomatic patients.

CDC continues to work with state health departments to develop and improve strategies and operational plans to respond to a pandemic influenza event. The Division of Strategic National Stockpile (DSNS) supports state and local pandemic influenza preparedness activities through technical assistance. DSNS program services consultants (PSCs) work one-on-one with state and local preparedness planners in the 62 project areas to help them prepare to receive and distribute pandemic influenza countermeasures to local hospitals and treatment facilities. One of the main functions of these PSCs is to conduct annual technical assistance reviews to assess state and local public health agencies' ability to receive, distribute and dispense Strategic National Stockpile (SNS) assets, including pandemic influenza countermeasures (which includes such items as antiviral drugs, personal protective equipment, and respiratory protection devices). DSNS also participates in state, local, tribal and territorial SNS exercises to evaluate designated receive, stage and store (RSS) sites and point of dispensing (POD) operations and provide assistance and guidance for further planning.

The coordinated response to the 2009-H1N1 outbreak marks a great improvement in the nation's public health response capabilities from just a few short years ago. Investments in public health preparedness have made a tremendous difference and, as noted, continue to be improved upon; however, gaps do still exist. A recent Association of State and Territorial Health Officials (ASTHO) survey noted that the public health workforce lost close to 12,000 jobs in the past year. Given these statistics and the impact the current economy has taken on state budgets, having enough public health workers at the ready to deliver medicines and medical supplies during an emergency, such as a possible second wave of a more virulent H1N1 virus, could be a challenge for states.

**2b. Do we have an adequate health care workforce in place, or ready to be called upon on a volunteer basis, to administer these drugs to those who fall ill?**

**Response:** Volunteer health professionals are available to assist their local communities and states through the Medical Reserve Corps (MRC) program and the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) program.

The Medical Reserve Corps (MRC), managed out of the Office of the Surgeon General, is a national network of 820 units in all 50 states and several territories. These units are community-based and function as a way to locally organize and utilize volunteers who want to donate their time and expertise to prepare for and respond to emergencies and promote public health

throughout the year. There are currently 178,311 MRC volunteers dedicated to meeting the needs in their local communities.

The Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) program is administered by the Office of the Assistant Secretary for Preparedness and Response (ASPR). The program is establishing a national network of state-based programs to register and verify the credentials, certifications, licenses, accreditations, relevant training, and hospital privileges of health professionals who volunteer to provide health services during a disaster or public health emergency. The ESAR-VHP programs register and verify the identity, credentials, and qualifications of volunteers in advance of an emergency. The purpose of the national network is to: 1) give all states the ability to quickly identify and better utilize health professionals in their state during disasters and public health emergencies; and 2) enable the sharing of pre-registered and credentialed health professionals across state lines and nationally. ESAR-VHP is being implemented in all 50 states and all territories. There are currently 148,794 registered ESAR-VHP volunteers.

Of the MRC units, 587 (74%) report they are involved in their local community's Pandemic Flu Planning process and 714 (90%) report they have conducted or are planning activities related to establishing points of dispensing sites where medications may be distributed to large numbers of the population. Furthermore 508 (64%) MRC units report they are involved in planning for local distribution of products received from the Strategic National Stockpile.

Should a pandemic on the scale of 1918 occur, MRC and ESAR-VHP volunteers will play a critical role in distribution of antiviral medication. However, it is unlikely they would they would provide an adequate healthcare workforce to fully address the need.

It is very difficult to predict the number of volunteers who would be available to administer medications. Numerous reports have stated hospital, public health, and emergency response agencies will be relying upon the same people. States may not allow their volunteers to participate in a federally coordinated response if there is an expectation that they may be needed in healthcare facilities in their own communities and states. Additionally, there are significant hurdles in regarding the recruitment of MRC volunteers and the establishment of new units. For example, the lack of clear and consistent legal protections for the MRC units and volunteers, other than when they are hired by HHS as intermittent employees, has been identified by the local leaders as a factor inhibiting the establishment of MRC units in their jurisdictions, and as the primary limiting factor in the recruitment of MRC members (especially physicians and other medical professionals).

**Post-Hearing Questions for the Record  
Submitted to Rear Admiral Anne Schuchat, M.D.  
From Senator Susan M. Collins**

**“Swine Flu: Coordinating the Federal Response”  
April 29, 2009**

- 1. Over the past decade, Congress has allocated significant funding to DHS and CDC to address a potential pandemic, but no point-of-care diagnostic tool is being utilized for this outbreak as funding has been spent primarily on vaccines. An effective diagnostic tool could be useful in containing an outbreak if it can quickly identify those with the virus whether at the border or in spotting the worried well filling emergency rooms during an outbreak. Do you believe that this is a gap in our preparedness for spotting a potential epidemic and preventing a pandemic?**

**Response:** HHS and CDC have received funds to promote the development of improved point-of-care diagnostic tests that could be used to identify individuals with influenza. While there are many commercially available point-of-care tests, none of them differentiates the subtypes of influenza A viruses nor are they able to identify the subtype of novel influenza viruses such as the 2009 H1N1 virus. However, the Naval Health Research Center (NHRC) has been conducting an IRB-approved study on an investigational diagnostic test for influenza, supported by CDC and BARDA. The antigen detection device is manufactured by Mesoscale Diagnostics and is currently in clinical trials at multiple sites in the United States; NHRC is one of those sites. It was this device at this site that, in April 2009, detected the first case of human novel H1N1 (A/CALIFORNIA/04/2009) in the United States. This patient presented to a Navy-affiliated clinic participating in the clinical trial in San Diego with respiratory illness and, based on presenting factors, was entered into the study. The result of the patient’s investigational diagnostic test detected an influenza A virus that could not be subtyped by the Mesoscale Diagnostics’ device, indicating that a novel influenza virus might be the cause of the infection. In compliance with the study protocol, the patient’s specimen was sent to The Marshfield Clinic in Wisconsin which serves as the central reference laboratory for the Mesoscale clinical trial. At The Marshfield Clinic, the patient’s specimen was tested using polymerase chain reaction (PCR) and a non-subtypeable influenza A virus was again detected. The specimen was then sent to the Wisconsin state laboratory for additional testing, in accordance with the study protocol and with current public health reporting requirements. The state lab was also unable to subtype the specimen and forwarded it to the U.S. Centers for Disease Control and Prevention (CDC) for assistance. Using more complicated laboratory methods, CDC identified the specimen as the first identified U.S. case of human novel H1N1 of swine origin.

In addition, to decrease the time needed to detect and report cases of influenza virus infection, CDC has:

- Obtained FDA clearance for a CDC-developed high throughput real time polymerase chain reaction (rRT-PCR) test to rapidly detect influenza viruses and differentiate subtypes. This collaboration among CDC, state health departments, and industry has served as a model to bring new molecular tests to broader availability. This effort greatly streamlined the development and dissemination of kits to diagnose the novel H1N1 virus.
- Expanded the network of reference laboratories capable of diagnosing influenza and differentiating between seasonal and novel influenza viruses, including the diagnosis of the novel H1N1 virus, in the United States and globally by training more than 40 state public health laboratorians and conducting 25 trainings for international health professionals in coordination with the World Health Organization National Influenza Centers in Africa, Asia, and South America in FY 2008.
- Awarded approximately \$33.5 million to develop new diagnostic testing devices for use in hospital laboratories and doctors' clinics that detect seasonal and potential pandemic viruses.
- Developed a real time PCR assay that will specifically detect the novel 2009 H1N1 viruses.
- Deployed novel H1N1 diagnostic rRT-PCR kits with primers/probes and control plus needed reagents to 260 laboratories in 142 countries, April - May 2009
- Utilized the Influenza Reagent Resource, established by CDC in 2008, to provide viruses and test kits to over 500 researchers, developers, and public health officials for improved detection of influenza cases, as well as to promote research and development of new vaccines, antiviral drugs, and diagnostic tests. CDC-IRR serves as a source of reagents for qualified laboratories to provide surge support. During pandemics, laboratories play a critical role in detecting and confirming cases, characterizing viruses, monitoring the progression of the pandemic, and selecting vaccine strains.



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May 11, 2009

The Honorable Joe Lieberman, Chair  
Senate Committee on Homeland Security and Governmental Affairs  
340 Dirksen Senate Office Building  
Washington, DC 20510

RE: Swine Flu: Coordinating the Federal Response hearing held on April 29, 2009

Submitted via email to [trina\\_tyrer@hsgac.senate.gov](mailto:trina_tyrer@hsgac.senate.gov)

Dear Chairman Lieberman:

On behalf of the Humane Society of the United States (HSUS), the country's largest animal protection organization, and our more than 11 million supporters nationwide, I thank the Homeland Security and Governmental Affairs Committee for convening a hearing to review the initial response to swine flu, and I submit this letter for inclusion in the April 29 hearing record.

In view of the serious global public health risks posed by the recent outbreak of "swine flu" (influenza virus A subtype H1N1), the HSUS urges federal officials to undertake a full investigation into the role of industrial intensive farm animal production operations in the emergence of the burgeoning pandemic in Mexico. The investigation should definitively determine the cause of the outbreak and identify the risk of further emergence of highly pathogenic influenza strains from intensive farming practices.

There is strong scientific evidence that the intensive farming of pigs may play a significant role in the development of highly pathogenic strains of influenza. The U.N.'s Food and Agriculture Organization's 2007 report *Industrial Livestock Production and Global Health Risks* notes that "[i]ndustrial pig and poultry production with its geographic intensity and being coincident for the two species, and with the regular movement of animals between production stages provides significant opportunities for interactions between large populations of confined poultry and/or pigs and thus has potential consequences for the development and transmission of some zoonotic disease agents. The proximity of thousands of confined animals increases the likelihood of transfer of pathogens within and between these populations, with consequent impacts on rates of pathogen evolution" (emphasis added). The report also refers to the U.S. Council for Agriculture, Science and Technology, which has warned that a major consequence of the industrial farm animal production systems that are customary in the United States is that they potentially allow the rapid selection and amplification of pathogens.<sup>1</sup>

<sup>1</sup> [www.fao.org/ag/AGALInfo/projects/en/ppipi/docarc/rep-hpai\\_industrialisationrisks.pdf](http://www.fao.org/ag/AGALInfo/projects/en/ppipi/docarc/rep-hpai_industrialisationrisks.pdf)

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Intensive pig production facilities provide the optimum conditions for viral mutation and transmission, with thousands of pigs crowded together in a closed, stressful, unhygienic environment, highly conducive to the transmission of a contagious disease. The risks arising from disposal of large quantities of excreta and other waste from an infected premises are also significantly increased in operations with large pig populations—particularly where manure lagoons are accessible to external vectors such as wild animals, birds, and flies, or where the waste disposal may contaminate local water sources.

Genetic selection of pigs for faster growth rates and higher meat yields has left the animals' immune systems less able to cope with infections; this, together with the high degree of genetic uniformity in the population, facilitates spread of the virus.

The evidence indicates that once a new and highly virulent strain of influenza has emerged, it can be spread in various ways, including movement of pigs and pig products, associated vehicles, and people. When assessing another strain, H5N1 highly pathogenic avian influenza (HPAI), many experts view the global trade in poultry and poultry products as the major cause of the spread of this HPAI. An editorial in *The Lancet* in April 2006 stressed that the movement of poultry and poultry products or infected material from poultry farms such as animal feed and manure is far more likely to be perpetuating the spread of the virus than wild birds. Indeed, the geographical spread of the disease does not correlate with bird migratory routes and seasons; instead, the pattern of outbreaks follows major road and rail routes.

In conclusion, the balance of scientific evidence suggests that the role of industrial intensive farm animal production should be fully considered when assessing the origin of the current Mexico outbreak, especially in light of the U.S. Centers for Disease Control and Prevention's genetic analysis of the virus, which shows the primary progenitor of the H1N1 virus was a triple hybrid pig/human/bird virus first identified in industrial pig operations in the United States in 1998. The global consequences of a human influenza epidemic for human health and global trade are of such significance that it is essential that the outbreak's emergence is fully understood, thus minimizing the potential for future pandemics.

Thank you for the opportunity to submit comments on these important issues affecting public and animal health. We look forward to working with the Committee to address these concerns.

Sincerely,



Wayne Pacelle  
President and CEO

**H1N1 Flu: Protecting Our Communities**  
**Homeland Security and Governmental Affairs Committee Field Hearing**  
Chairman Joe Lieberman  
September 21, 2009

**Good morning to everyone and welcome to this field hearing of the U.S. Senate Homeland Security and Governmental Affairs Committee at which we will examine Connecticut's preparedness for a fall resurgence of the H1N1 influenza virus.**

**I appreciate the participation of all of our witnesses today as we sort through the challenges of government agencies and private and public institutions that must collaborate with one another and clearly communicate with the public so that the business of commerce, education, and life in general can proceed without major interruptions should H1N1 take hold in Connecticut.**

**We are holding this hearing now because it is the beginning of a very unusual and threatening flu season. But September is also National Preparedness Month, and therefore a good time to remind everyone that you contribute to the well being of your own communities when you take time to inform yourself about existing threats and make personal or family plans to deal with those threats, should that be necessary. Preventing the spread of the flu is something that every single person can and must help with, and I hope that this hearing further inspires people from all walks to life to do their part.**

**As everyone knows by now, the threat we are talking about today, the H1N1 virus, is a fast-spreading disease that was first detected last spring. It reached pandemic proportions worldwide over the summer and appears to be making a comeback as the traditional flu season begins.**

**The Centers for Disease Control (CDC) has estimated that a million people in the U.S. have become ill with H1N1 flu, and we can safely guess that millions more have likely been exposed to the virus since then. We know that 9,000 have been hospitalized, and 593 have died. Here in Connecticut, about 2,000 cases have been confirmed and nine people have died.**

**Fortunately, unlike other crises we have faced, pandemic flu is one we have anticipated and planned for. In response to global outbreaks of Avian Flu, West Nile Virus, and SARS, the CDC developed a strategy for a coordinated national response to the growing threat of infectious diseases. The Homeland Security Council also published a national strategy for how to respond to a pandemic influenza. And, with support from the Department of Health and Human Services and the Department of Homeland Security, states too have developed plans for addressing pandemic flu.**

**Following the spring outbreak, the medical and pharmaceutical communities has had time to study the H1N1 virus and to start producing a vaccine. And agencies at all levels of government have gotten advance warning that they need to be prepared for the**

possibility of a more virulent strain of the virus this fall - even though as of today, thankfully, that has not happened. We hope that those agencies have used their time wisely.

Today, I will ask our witnesses representing state and federal agencies what their H1N1 response plans are, whether they are working together, and what else can be done to address a large outbreak of H1N1. I will ask our witnesses representing the public, educational institutions and business if the government planning has been clear and constructive and what if anything else they would think should be included.

It appears that the federal government can begin delivery of the H1N1 vaccine to states as early as the week after next. Connecticut is expected to receive about 500,000 doses by mid October, which will be reserved for those most at risk: pregnant women, young children, daycare workers, health care and emergency medical personnel, and those with certain conditions such as diabetes and immune deficiencies.

The federal government is also providing money to states to help prepare for the fall flu season and to administer the vaccine. According to Admiral Milner, our witness today from the Department of Health and Human Services, Connecticut has received \$6.4 million of this emergency public health funding and can expect an additional \$10.4 million.

At this point, the state appears to be on track to stay out in front of a broad H1N1 outbreak. We are fortunate that, so far, most cases of the virus have continued to show the same mild to moderate symptoms as we observed last spring, but outbreaks of infectious diseases are hard to predict, so circumstances could still change dramatically over the coming weeks and months. And remember, nine people have already died from H1N1 flu, so this was not a mild outbreak for their families.

Therefore, we must remain on heightened alert, continue to take preventative action, work together and hone communications with the public, and – while hoping for the best – we must prepare for the worst. I look forward to hearing the testimony of our witnesses today to get a clear sense of Connecticut's preparedness for this potentially dangerous influenza strain and to see what our Committee and the Congress can do to help.

Thank you.

**Testimony of  
RADM Michael R. Milner, USPHS  
before the  
Committee on Homeland Security and Governmental Affairs  
United States Senate  
on  
H1N1 Flu: Protecting Our Communities**

Good morning Chairman Lieberman, Senator Collins and members of the Committee.

I am Rear Admiral Michael Milner, U.S. Public Health Service and the Health and Human Services Regional Health Administrator for Region 1 (New England) based out of Boston, Massachusetts.

I appreciate the opportunity to testify today regarding the work our federal government, HHS and my regional office have done and are doing in support of our Northeast states and the State of Connecticut specifically to prepare for the pandemic 2009 H1N1 influenza virus this fall.

By way of background, I thought you should know about my role and responsibilities as the Health and Human Services Regional Health Administrator and how I came to be before you today. I have served as the senior federal public health official for the 6 New England states since August 2003 and work directly for the Assistant Secretary for Health, Dr. Howard Koh. Additionally, I serve as the Senior Federal Health Official for both HHS Regions 1 and Region 2 to the Regional Coordination Team Leader in support of the Department of Homeland Security.

Since the initial spring outbreak of 2009 H1N1 influenza, the virus has triggered a worldwide pandemic, and has been the dominant flu strain in the southern hemisphere during its winter flu season. The evidence to date shows that the virus has not changed to become more deadly. Unlike our typical seasonal flu, we continued to see flu activity in the United States over the summer, notably in summer camps. More recently, we have seen an increase in 2009 H1N1 influenza activity in several states and expect this to continue across the United States during the coming months. As fall begins, we anticipate that even more communities may be affected than those that saw cases this past spring and summer. In addition, communities may be more severely affected, reflecting wider transmission and causing potentially greater impact. Seasonal influenza viruses may cause illness concurrently with 2009 H1N1 this fall and winter and it will not be possible to determine quickly if ill individuals have 2009 H1N1 influenza, seasonal influenza, or other respiratory conditions based on symptoms alone. It is also difficult to predict the severity of the disease that we will see in the coming months from either 2009 H1N1 or seasonal influenza. Influenza is an unpredictable disease and we know that things will change and we will learn more throughout the fall.

Slowing the spread and reducing the impact of H1N1 and seasonal flu is a shared responsibility, and we all need to plan for what would need to be done when the flu impacts our State, community, school, business or home this fall.

The Northeast State Health Officers (SHO's), Emergency Managers, Communications Directors, State Public Health Preparedness Directors along with a federal partners team consisting of ASPR Emergency Coordinators, CDC Project Officers, FEMA and DOD planners and DHS/HHS leaders, have been engaged in very aggressive, detailed Pandemic Planning through face to face meetings, active listening sessions with stakeholders and conducting joint exercises. This pandemic planning process began in early 2006 and has resulted in several multi-day, multi-sector planning events, the first pandemic executive communications regional exercise, the first regional FEMA Joint Field Office operational exercise in the country, several joint state Table Top Exercises, development of the first regional federal Concept of Operations document for JFO operations during a pandemic and a series of regular dialogues between regional state response agency leaders. Our combined efforts have been centered on enhancing interstate and inter-regional communication strategies, sharing mitigation strategies, developing better integrated plans, improving existing scientific guidance, exercising our plans, improving our regional critical information requests so as to reduce the burden on our state partners, and evaluating our outcomes with the goal of building resilience and reducing the impact of a pandemic on our society.

Beginning April 24<sup>th</sup>, 2009 and continuing through early June, 2009, the regional federal team had daily contact with our State Health Officers and their support teams. Because of our daily early morning conference calls, we were able to communicate to our HHS leaders in real time the "ground truth" of the characteristics of the emerging 2009 H1N1 virus and the impact of federal guidance to our states and local governments related to school closures, epidemiologic testing and surveillance practices, and the use of Personal Protective Equipment and antiviral countermeasures. This allowed for faster modifications of our federal guidance to better match community mitigation efforts with the true viral impact of 2009 H1N1. I personally believe that the Northeast States were at the tip of the spear in the early days of novel H1N1 outbreak and that the strong partnership that we developed here helped shape the federal messages and the tone and tenor of our federal response. Over the summer we participated in weekly calls with our SHO's who continued to help shape the federal guidance for things like school and camp containment strategies and lab testing protocols. I hold all of my colleagues from the Departments of Health, Emergency Management, and Public Health Preparedness in the Northeast states and especially Connecticut in the highest regard. We work together to resolve perceived or real conflicts, share ideas, improve our understanding of each others processes and build trust for the benefit of all citizens of Connecticut and the entire Northeast.

CDC's Efforts:

The nation's H1N1 response builds upon gains states and localities have made in all-hazards preparedness from past years of federal funding, including CDC's Public Health Emergency Preparedness (PHEP) cooperative agreement.

Since 2002, the PHEP cooperative agreement has provided nearly \$7 billion to support preparedness nationwide in state, local, tribal, and territorial public health departments. The PHEP program uses an all-hazards approach to help ensure that public health departments have the capacity and capability to effectively respond to the public health consequences of not only terrorist threats, but also infectious disease outbreaks, natural disasters, and biological, chemical, nuclear, and radiological emergencies. PHEP accomplishments include:

- ✓ All states have public health emergency response plans in place (few states had such plans in 2001).
- ✓ All states have plans in place for receiving and distributing assets from the Strategic National Stockpile and are exercising those plans.
- ✓ All states have crisis and emergency risk communication plans.
- ✓ All states have individuals assigned to evaluate urgent disease reports 24 hours, 7 days a week, 365 days a year.
- ✓ All states have protocols in place to activate the public health emergency response system 24 hours, 7 days a week, 365 days a year.
- ✓ Participation in the Cities Readiness Initiative (CRI) has increased from 21 cities in 2004 to 72 cities today. CRI aids state and local officials in developing plans that support mass dispensing of needed drugs and medical supplies to 100 percent of the identified population within 48 hours to avert mass casualties during a large scale public health emergency, such as a bioterrorism attack.

Now, CDC is working to support states and localities with 2009 H1N1 preparedness and response activities in three major areas: 1) administration of supplemental emergency funds totaling approximately \$1.35 billion; 2) targeted technical assistance; and 3) distribution of pandemic influenza pharmaceuticals and supplies.

Area 1: Public Health Emergency Response (PHER) Supplemental Funding

CDC is administering approximately \$1.35 billion through the Public Health Emergency Response (PHER) grants to upgrade state and local 2009 H1N1 influenza preparedness and response capacity. This funding was appropriated by Congress in June 2009 through the Supplemental Appropriations Act, 2009, and the 2009 H1N1 funding has been distributed in phases. The 62 awardees include 50 states; 8 territories and freely associated states; and 4 localities (Chicago, Illinois; Los Angeles County, California; New York City, New York; and Washington, D.C.). These funds are building upon the work of previous federal pandemic preparedness funding provided by Congress.

PHER Phase I

Phase I funding of \$260 million is intended to help awardees assess their current capabilities in pandemic influenza response and to address remaining gaps in two focus areas as described below.

- Focus Area 1: \$195 million - Vaccination, Antiviral Distribution/Dispensing and Administration, and Community Mitigation Activities
- Focus Area 2: \$65 million - Laboratory, Epidemiology, Surveillance Activities

**Connecticut's share of these funds is \$2,998,173.**

PHER Phase II

An additional \$248 million in PHER Phase II funding has been awarded to supplement the original \$260 million and is intended to provide additional resources to accelerate mass vaccination planning and implementation preparedness activities. Phase II funding also may be used for vaccine delivery, vaccine administration, and related communications planning and implementation.

**Connecticut's share of Phase II funding is \$3,391,156.**

PHER Phase III

A total of \$846 million in PHER Phase III funding will be awarded for implementation of the 2009 H1N1 influenza mass vaccination campaign, expected to begin in October, at the state, local, tribal, and territorial levels.

**Connecticut's share of these funds is \$10,492,903.**

Area 2: PHER Gap Assessments and Targeted Technical Assistance

On August 31, PHER awardees submitted detailed gap assessments intended to identify and report current and anticipated gaps in 2009 H1N1 influenza planning and response functions. As we speak here today, CDC staff are completing a rapid analysis of the gap assessments. This will provide a preliminary snapshot of current gaps to inform decision-making and enhance planning and coordination at the local, state, and federal levels. It will provide data needed to develop and deliver targeted 2009 H1N1 technical assistance by HHS to our states and jurisdictions. We are very anxious to see this analysis and begin the work to address identified gaps.

Area 3: Pandemic Influenza Countermeasures

During the spring 2009 H1N1 response, CDC's Strategic National Stockpile (SNS) delivered more than 11 million regimens of antiviral drugs, 12.5 million surgical masks, and 25 million N-95 respirators to all 62 project areas in 7 days. This material was pre-deployed as the novel H1N1 virus event was unfolding, even before we knew the full extent of the viral outbreak. These assets comprised 25% of the states' allotted pandemic influenza allocations and was the first large scale distribution of its kind. The SNS is currently working with states to determine future needs.

**The Connecticut SNS allocation of antiviral drugs is nearly 520,000 regimens.**

Additionally, HHS is collaborating with representatives from the pharmaceutical and personal protective equipment industries (manufacturers, wholesalers and distributors), retail pharmacies, and public health federal and non-federal partners on a project to assist federal, state and local public health leaders gain visibility of the commercial supply chain for critical influenza countermeasures. Such visibility will allow for better public health decision-making when it comes to procuring, distributing, and dispensing these critical medical assets.

ASPR Efforts:

The other HHS division which has been providing resources and assistance to the states is ASPR, the Assistant Secretary for Preparedness and Response.

Hospital Preparedness Program (HPP)

Since 2002, the Hospital Preparedness Program (HPP) has provided more than \$3.2 billion to fund the development of medical surge capacity and capability at the state, sub-state/regional and local levels, through enhanced planning, equipping, training and exercising. The program has made considerable investments in building the healthcare preparedness and response capabilities required during an incident resulting in mass casualties, and is committed to performance measurement.

As a result of HPP funds awarded to States and Territories, hospitals and other healthcare systems have improved their capability to:

- Exercise and improve preparedness plans for all-hazards including an influenza pandemic.
- Track patient, bed and resource availability using electronic systems;
- Engage with other responders through interoperable communication systems;
- Develop healthcare partnerships and coalitions;
- Develop ESAR-VHP (Emergency System for Advance Registration- Voluntary Health Personnel) systems;
- Appropriately train healthcare workers using an all-hazards approach to emergencies,
- Protect healthcare workers with proper equipment;
- Install equipment necessary to decontaminate and isolate patients;
- Develop fatality management and hospital evacuation plans;
- Coordinate statewide and regional and exercises.

*State of Connecticut- HPP*

FY 2009 Pandemic Influenza Healthcare Preparedness Improvements for States

Total Funding - \$1,035,479

Connecticut has come a long way in its planning efforts for an influenza pandemic using this federal funding over the past seven years. All of the hospitals in the state have plans in place for pandemic influenza operations, hospital vaccination programs and continuity of operations; it is absolutely necessary to assure that all are in fact operational and scalable to the specific facility. During the H1N1 outbreak response this spring, gaps in some of the plans and needed supplies were found. As Connecticut and other states wait to see what happens with the Flu Season this fall and specifically with the impact of this 2009 H1N1 virus, there is an urgency to fill in these gaps, so the hospitals can continue to limit the spread of this virus in order to protect and maintain their workforce, to prevent hospitals from becoming disease amplifiers and to protect non-flu hospitalized patients from infection. It is essential that every hospital be evaluated to see where they are in terms of these plans, so the state is focusing on evaluating the current status of plans and supplies.

To continue to provide the highest quality healthcare to all citizens, Connecticut proposed in their FY 2009 Pandemic Influenza application to use the funding (\$1,035,479) to develop goals, objectives and activities in the following priority areas;

**Objective #1: Maintain a robust healthcare system throughout the influenza pandemic by implementing activities related to healthcare workforce protection.**

- Mass Vaccination for employees
- Employee Workplace Policies
- Adequate Personal Protection Equipment (PPE) Systems

**Objective #2: A comprehensive strategy for the optimization of healthcare will be maintained throughout the influenza pandemic.**

- Healthcare System Decompression
- Alternate Care Facility/Site Capability
- Situational Awareness
- Media Strategies

**Summary:**

In summary, in the months since the 2009 H1N1 threat developed, our federal team has seen an incredibly strong commitment from our colleagues on this panel to meet the challenges that this novel virus presents. Connecticut's planning efforts for 2009 H1N1 and seasonal influenza vaccination programs to target our citizens most at risk has been exemplary. They continue to improve guidance to health professionals, school administrators, parents, the business community and all Connecticut citizens which take the latest scientific evidence into consideration. They have worked very hard to make sure that Connecticut's most vulnerable citizens and those who are at greatest risk are included in the messaging and outreach.

I am sure in the upcoming rounds of testimony my state colleagues will describe their specific efforts which they have implemented and I am confident that they have been excellent stewards of the federal resources which have been and are being distributed. I

have seen their creativity and resourcefulness first hand and know that they are doing everything possible to address this challenge. I recognize that they have significant challenges imposed by virtue of economic downturn and resulting state budget and staffing shortfalls. Despite these real challenges, I am extremely comfortable that the planners and operators in Connecticut have excellent strategies in place to meet their missions. I am also extremely comfortable in the knowledge that our regional state partners know that they can count on our federal team to assist them in any way that we can in the coming weeks and months.

I appreciate this opportunity to address your committee and thank you for the privilege to continue to serve my nation in this capacity. I am available to answer any questions you may have at this time.

**FIELD HEARING**

**STATEMENT OF MATTHEW L. CARTTER, MD, MPH**

**STATE EPIDEMIOLOGIST**

**STATE OF CONNECTICUT**

**DEPARTMENT OF PUBLIC HEALTH**

**BEFORE THE**

**COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS**

**UNITED STATES SENATE**

**21 SEPTEMBER 2009**

**HARTFORD, CONNECTICUT**

Good morning Senator Lieberman, Senator Collins, and members of the Committee. Thank you for inviting me here today.

I am Matthew L. Cartter, MD, MPH; State Epidemiologist for the Connecticut Department of Public Health. I am here to provide you with an update on the current status of the influenza pandemic in Connecticut and the plans to distribute the newly licensed Influenza A (H1N1) 2009 Monovalent vaccines to the residents of the state.

As a preliminary matter, I will defer to my colleague from the Connecticut Department of Emergency Management and Homeland Security, Commissioner Peter Boynton, on the State of Connecticut's activities related to planning and preparedness; information sharing and outreach; and collaboration.

As of September 16, 2009, 1,992 Connecticut residents have tested positive for 2009 pandemic influenza A (H1N1) infection. This number represents the tip of an iceberg. Most people who became ill with this new influenza virus were not tested, especially after May when community transmission of the H1N1 virus was established in Connecticut.

Here in Connecticut, the first wave of this pandemic lasted about 8 weeks. The first 4 H1N1-related hospitalizations were in the last week of May, 104 persons were hospitalized in June, and 29 persons were hospitalized in the first three weeks of July. Since then, there have only been two hospitalizations reported to us. Nine Connecticut residents with H1N1 influenza infections have died: 6 persons died in June and 3 in July.

The virus did not disappear over the summer; there were cases of this new influenza infection in summer camps. One of the systems that we use to track influenza-like illness in the community is called the Hospital Emergency Department Syndromic Surveillance (HEDSS) System. Developed in 2004, this system receives daily electronic reports from more than half of Connecticut's acute care hospitals. During the week ending September 12, 2009, the percentage of total emergency department visits for "fever/flu" syndrome category remained above the "baseline" for the same week in 2007 and 2008 for the third week in a row. This strongly suggests to us that the transmission of H1N1 influenza virus has been increasing in Connecticut for the last 3 weeks. We are also aware of confirmed cases of influenza A on several college campuses. In Connecticut, the second wave of the pandemic is about to start.

Influenza pandemics differ in severity. This pandemic is at least as severe as seasonal influenza and appears, so far, to be similar to the 1957 influenza pandemic. Over the summer, the federal Centers for Disease Control and Prevention (CDC) and state and local health departments issued updated recommendations on community mitigation, infection control, and the use of antivirals in anticipation of the next wave. State public

health laboratories, including our own here in Connecticut, are ready to provide the testing needed to guide our public health interventions. Communication and public education plans are in place.

The best way to prevent influenza is with a vaccine. In anticipation of the Influenza A (H1N1) 2009 Monovalent vaccines, state and local health departments across the country have developed vaccine distribution plans. Our plan for Connecticut is included in my written statement and available on our website ([http://www.ct.gov/ctfluwatch/lib/ctfluwatch/h1n1/h1n1\\_vaccine\\_dist\\_plan\\_809.pdf](http://www.ct.gov/ctfluwatch/lib/ctfluwatch/h1n1/h1n1_vaccine_dist_plan_809.pdf)).

On August 31<sup>st</sup>, we began a pre-registration process for recruiting licensed healthcare providers statewide who would be interested in administering H1N1 vaccine to pre-register with the state Immunization Program.

The main goal of the pre-registration process is to have vaccine available in a variety of venues composed of both public and private entities to ensure that H1N1 vaccine is delivered to as many recommended individuals as possible.

There is no cost to pre-register and registered providers are not committed to provide vaccine. Pre-registration is necessary to collect the shipping and contact information to allow the state to have vaccine shipped directly to each individual provider's office. Providers will have the opportunity to order vaccine as it becomes available.

To pre-register to receive vaccine, providers must sign a Provider Agreement and complete a provider profile. The provider agreement contains a list of terms and conditions defined by federal and state authorities that providers must sign off on in order to receive H1N1 vaccine from the state. The provider profile will be used to collect shipping and contact information.

Once pre-registered, providers will be provided with updates, forms and ordering instructions for receiving vaccine. Vaccine will only be shipped to providers who have pre-registered and completed a vaccine order form.

As of September 16<sup>th</sup>, 947 providers have signed on. Providers include OB/GYN offices, pediatricians, family physicians, internists, hospitals, community health centers, local health departments, school based clinics, pharmacies, and occupational and retail settings.

The state has 41 mass dispensing areas. Each mass dispensing area is led by a local health department that coordinates vaccination efforts with public health entities, community health organizations and private sector providers.

Nationally, there will be approximately 45 million doses of H1N1 vaccine available by mid-October. In Connecticut, we expect to receive approximately 750,000. We will target the sub priority population groups according to CDC guidance and expand the program as more vaccine becomes available.

There are many challenges ahead of us. Thank you for the opportunity to discuss the public health response to the 2009 influenza pandemic. We in Connecticut are grateful for federal support of our pandemic influenza preparedness activities. I would be happy to answer any questions you have at this time.

# **H1N1 Vaccine Distribution Response Plan**

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## **CONNECTICUT DEPARTMENT OF PUBLIC HEALTH**

**August 2009  
8/11/2009**

8/11/2009

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**TABLE OF CONTENTS**

- I. Introduction.....2
- II. Planning Assumptions.....2
- III. Concept of Operations .....4
  - A. Allocation..... 4
  - B. Vaccine Supply..... 4
  - C. Immunogenicity and Number of Doses ..... 5
  - D. Receipt of Vaccine ..... 5
  - E. Duration of H1N1 Vaccination Campaign..... 5
  - F. Priorities for Shipping ..... 6
  - G. Hospitals..... 6
  - H. All other Providers..... 6
  - I. Communications..... 6
  - J. Recordkeeping and Vaccine Tracking ..... 8
  - K. Adverse Events Monitoring..... 9
- IV. ROLES AND RESPONSIBILITIES ..... 10
  - A. DPH .....10
  - B. Mass Dispensing Areas (MDAs) .....11
  - C. Community Healthcare Providers (i.e., pediatricians, community health centers, school based health centers, Visiting Nurse Associations [VNAs]).....11
  - D. Hospitals.....12
  - E. Other Mass Vaccinators .....12
- V. Planning Scenarios to target high-priority populations for vaccination ..... 13
- VI. Plan Development and Maintenance ..... 14
- VII.A Attachments ..... 14
  - A. Table 1: Populations to be vaccinated and resources to perform vaccination ....15
  - B. Figure 1: Priority Populations for Vaccination Based on Limited Supply According to CDC ACIP Sub-Group Planning Scenarios. ....18
  - C. Figure 2: Priority Populations for Vaccination Based on Adequate Supply According to CDC ACIP Sub-Group Planning Scenarios. ....19
  - D. Figure 3: CT Department of Public Health H1N1 Vaccine Delivery Schematic....20

## I. INTRODUCTION

In April 2009, the first cases of a novel influenza virus (H1N1) were identified in the US. In June 2009, the World Health Organization upgraded the worldwide alert to a Phase 6, the pandemic phase. Phase 6 is characterized by sustained community level outbreaks in at least one other country in another WHO region. Designation of this phase indicates that a global pandemic is under way. In response to the above, the Centers for Disease Control and Prevention (CDC) began the process of contracting for the production of a novel H1N1 influenza vaccine.

In the fall of 2009, two different types of influenza vaccine are expected to be recommended for persons in the United States: seasonal vaccine and a separate vaccine solely for protection from the novel H1N1 virus (hereafter referred to as the "pandemic virus") that emerged in the spring of 2009, too late to be included in the seasonal influenza vaccine production process. CDC anticipates the vaccine to be licensed and ready for distribution by the mid fall of 2009.

The following plan is a modification of the Connecticut Department of Public Health's Pandemic Plan of June 2008. This plan addresses the current situation and outlines vaccine administration and data collection scenarios.

## II. PLANNING ASSUMPTIONS

- Connecticut Department of Public Health (DPH) will follow the response approaches and guidelines developed by the federal government for the distribution of vaccines.
- The CDC, with guidance from the Advisory Committee on Immunization Practices, will identify priority populations for the limited early vaccine supply. DPH will use the CDC guidance and recommendations as the baseline for our in-state activities, with the understanding that we will need to recognize and address Connecticut-specific issues.
- Priority groups will be vaccinated sequentially, in other words, all persons in a given tier (and priority within a tier, if any) will receive one dose before the next rank and tier will begin vaccination.
- The federal government will procure and distribute H1N1 pandemic vaccine to the state for redistribution, at "no cost" to those being vaccinated.
- Funding will be available to reimburse providers for an administration fee for this vaccine. CDC will determine the fee.
- The DPH will receive a vaccine allocation based on Connecticut's proportion of the U.S. population (about 3.5 million doses or 1.159% of the national supply).
- Based on the three vaccine supply scenarios, Connecticut will receive an initial shipment of 463,706 doses (based on a supply of 40 million doses), 927,413

- doses (based on a supply of 80 million doses) or 1,854,825 doses (based on a supply of 160 million doses).
- Additional weekly allocations will be made as follows: 115,927 doses (based on 10 million doses), 231,853 doses (based on 20 million doses), or 347,780 doses (based on 30 million doses).
  - Vaccination will occur at the local level, with minimal disruption to public daily activities.
  - The vaccine will be a licensed product, so there will be no need for Investigational New Drug (IND) efforts or Emergency Authorization Use (EAU).
  - Two doses of pandemic vaccine will be needed with receipt of the second dose 4 or more weeks after the first dose.
  - An Immunization shot card will be provided to recipients who receive H1N1 vaccine for documenting vaccination that also includes a reminder that a second dose of H1N1 vaccine is needed to complete the series.
  - Vaccine supply will be limited at the beginning but will increase as time goes on. The vaccination process will be an on going long term effort, with the entire US population eventually being offered vaccine.
  - DPH will approach this vaccination effort as a non-emergency event. As such, there will not be a declaration of a civil emergency or a public health emergency by the Governor's Office, and DPH will need to follow all existing statutory and regulatory requirements for the State of Connecticut.
  - While DPH may blend elements from both the DPH Public Health Emergency Mass Vaccination Plan and the DPH Pandemic Plan, DPH's approach will be to develop an enhanced version of existing plans for seasonal flu vaccinations. As is the case with the annual vaccination program, DPH will use a combination of public and private assets to complete this mission.
  - The number of vaccine doses administered must be reported to CDC on a weekly basis, along with minimum data elements, in aggregate form by means to be determined.
  - Each vaccinator will be required to report any Adverse Events from vaccination to a DPH or CDC designee.
  - DPH will develop an enrollment and ordering process for vaccinators who will be using the vaccine.
  - Vaccine will be commonly distributed mostly in 10 dose vials. A smaller portion of the vaccine will be in pre-loaded syringes and a live attenuated nasal spray formulation.
  - CDC will provide ancillary vaccination supplies such as needles, syringes, and band-aids.
  - There will be no separate vaccine allocation for Native American tribal communities or retired Military and their dependents. Vaccine for these populations will be part of the state's allocation.
  - Consistent with past vaccination efforts, DPH will work with CDC and Local Health Departments to develop a communications plan.

**III. CONCEPT OF OPERATIONS****A. Allocation**

- Allocations to vaccinating agencies and health care providers will be determined by DPH subject to approval from the Governor.
- DPH will retain the authority to redistribute allocations after initial distribution based on supply and the course of the pandemic.
- Each of the 31 acute care hospitals and the VA Hospital in West Haven will receive an allocation determined proportionally by their pre-pandemic bed-based share for Tier 1 direct care hospital staff.
- H1N1 vaccine will also be allocated and made available to local health departments, visiting nurse associations, private physician offices, OB/GYN, Community Health Center, mass vaccinators (e.g., Maxim), and School Based Health Centers as it becomes available. Each location will receive weekly allocations of H1N1 vaccine based on doses made available to the state.
- Mass Dispensing Area Leads (MDA's) coordinate, collaborate and communicate with the local health departments/districts and community health care providers for their respective area to develop and carry out H1N1 Influenza Distribution Plan, in accordance with the state's plan.
- The Immunization Program will initiate a pre-registration process for targeted licensed immunization providers interested in administering H1N1 vaccine.
- There is no cost to pre-register and registered providers are not committed to provide vaccine, but they will be engaged in the process and receive email updates and vaccine planning information. They will have the opportunity to order vaccine as it becomes available.
- Pre-registration will collect the shipping and contact information necessary for the state to ship vaccine to the provider.
- As H1N1 vaccine becomes available providers will order vaccine through the DPH Immunization Program's Vaccine Order Form.
- Vaccine orders will be processed by Immunization Program staff daily and transmitted electronically to a third party distributor for shipment.
- Providers can order vaccine on a weekly basis for the duration of the pandemic.

**B. Vaccine Supply**

- Vaccine is expected to be ready for distribution by mid-fall. Based on the three vaccine supply scenarios, Connecticut will receive an initial shipment of 463,706 doses (based on a supply of 40 million doses), 927,413 doses (based on a supply of 80 million doses), or 1,854,825 doses (based on a supply of 160 million doses).
- Additional subsequent weekly allocations based on three initial vaccine supply scenarios listed above will be either: 115,927 doses (10 million doses), 231,853 (20 million doses), or 347,780 (30 million doses).

- The majority of vaccine will be distributed in multidose 5ml/10 dose vials although approximately 15% of vaccine may come in pre-filled syringes or nasal sprayers (Live Attenuated Influenza Vaccine (LAIV) for the pediatric population.

### C. Immunogenicity and Number of Doses

- Until the H1N1 pandemic vaccine strain is developed and tested, it will not be known whether a second dose of vaccine will be needed to achieve immunity in vaccinated persons.
- DPH will provide guidance and recommendations established by the CDC Advisory Committee on Immunization Practices (ACIP) regarding H1N1 vaccine administration that will include the appropriate immunization schedule, dosage and contraindications.
- If changes are made in the recommended number and timing of doses, information about vaccine administration will be communicated utilizing the Health Alert Network (HAN), the CT Flu Watch website ([www.ct.gov/ctfluwatch](http://www.ct.gov/ctfluwatch)) and blast fax and will be reflected in any protocols for vaccination distributed by DPH.
- DPH will post up-to-date educational materials for staff and vaccinees on second dose recommendations.

### D. Receipt of Vaccine

- All vaccine will be shipped directly to each provider location. Up to date shipping information will be maintained by the Immunization Program's Vacman software application.
- The Immunization Program will send an electronic file with all provider orders to the 3<sup>rd</sup> party distributor on a daily basis and receive a daily shipping log from the distributor on all orders sent out the previous business day.
- Pre-registration process for licensed immunization providers for receipt of H1N1 vaccine will include vaccine storage and handling requirements.
- The vaccine must be stored in a refrigerator at between 35<sup>o</sup>-46<sup>o</sup> F. Dormitory style refrigerators do not maintain consistent temperatures so vaccine will not be shipped to facilities with that type of unit.
- Immunization Program staff will be responsible for verifying that each location has a suitable storage unit and thermometer to record the temperature and is following standard vaccine storage and handling procedures.

### E. Duration of H1N1 Vaccination Campaign

- The H1N1 influenza vaccination campaign will take place over many months. Vaccine is expected to be available in mid-fall with vaccination efforts expected to continue into the following spring.
- Demand will exceed initial supply requiring careful control of vaccine distribution. Providers will need to vaccinate their patients based on CDC priority group recommendations. (attachment B & C – pages 18-19)

**F. Priorities for Shipping**

- Timing of shipping will follow the priority scheme for allocation according to priority groups identified by CDC.
- Pre-registration of providers will identify potential vaccinators for the priority groups.
- The vaccinators of priority groups will receive H1N1 vaccines for priority groups, depending upon available vaccine supply.

**G. Hospitals**

- Vaccines will be shipped to 31 acute care hospitals and the VA Hospital in West Haven to ensure that the medical providers with direct medical care responsibilities are promptly vaccinated according to priority groups identified by CDC.
- The 31 acute care hospitals will distribute vaccine to their own staff.
- Hospitals will use already developed smallpox vaccination/occupational medicine teams, space, and protocols for distribution within the hospital to priority staff. The latter can use the hospitals existing identification and security structures to match personnel against lists of prioritized persons.
- Cold chain, security, and recordkeeping will be maintained by the hospitals using pharmacy, security, and medical records staff and resources in accordance with their mass dispensing (smallpox) plans.

**H. All other Providers**

- Local health departments, visiting nurse associations, private physician's offices, OB/GYN practices, Community Health Centers, mass vaccinators, and School Based Health Centers would prioritize patients based on the Priority List in accordance with CDC guidance and vaccine recommendations (attachment B & C – pages 18-19).
- Cold chain, security, and recordkeeping will be the same as for the hospitals.

**I. Communications**

- The current structures and protocols noted in the state and local Public Health Emergency Communications Plans will be used to communicate content to the public explaining the rationale for vaccine distribution prioritization, when and where to go to be vaccinated, and the possible need for a second dose.
- A vaccination website providing vaccination information will be developed on the CT Flu Watch website ([www.ct.gov/ctfluwatch](http://www.ct.gov/ctfluwatch)) identifying priority populations, providing information on the vaccine, as well as any necessary documentation and where residents should go for vaccination. A link to this website will also be prominently posted on the DPH home page ([www.ct.gov/dph](http://www.ct.gov/dph)).
- Hotlines, such as Info Line (2-1-1), will be extensively employed to help inform the public and answer questions.

- Press releases will be developed and disseminated to media outlets using the Odyssey Document Delivery System.
- Thirty-second television and radio announcements will be developed informing the public that a vaccine is now available and directing them to visit the vaccination website, call United Way 211, or contact their provider for information on how to get the vaccine.
- DPH risk communication/public education materials and public service announcements are being translated into several languages. A web site specifically for local health is established for downloading materials for use. DPH will identify and refer to CDC resources as appropriate.
- DPH will utilize social media sites including Facebook and Twitter.
- Key populations to be addressed will be:

Healthcare providers

- A communication will be sent to targeted licensed physicians, local public health departments, hospitals, health care facilities, pharmacies, occupational health settings, etc., to gauge provider interest in participating in an H1N1 influenza vaccination campaign later this fall. Those who are interested in providing H1N1 vaccine will pre-register to receive vaccine when it becomes available. In addition communications will be distributed to physician associations and various health care organizations, e.g., American Academy of Pediatrics, CT State Medical Society, etc.

Priority populations

- Thirty-second television and radio announcements will be developed informing the public that a vaccine is now available and directing them to visit the vaccination website, call United Way 211, or contact their provider for information on how to get the vaccine.

Parents of school-aged children

- The DPH will provide a letter to the State Department of Education and Connecticut Association of Independent Schools identifying priority populations for vaccination and providing vaccination information.

Child Day Care Providers

- A letter with vaccination information will be sent to child day care centers/group day care homes and family day care homes.
- A parent letter will also be provided that programs can share with parents, which will contain general information and inform them on whom to contact to be vaccinated (local health department or private practitioner).
- The letter to day care centers/group day care homes will advise them that they may be contacted with an opportunity to become a vaccination site.

- A notice will be given to local health departments to consider utilizing licensed child day care centers/group day care homes as potential vaccination sites.

Special needs populations as identified by local health departments

- Local health departments will be responsible for reaching out to their special needs populations as identified in their plans

General public

- Thirty-second television and radio announcements will be developed informing the public that a vaccine is now available and directing them to visit the vaccination website, call Info Line 211, or contact their provider for information on how to get the vaccine.

**J. Recordkeeping and Vaccine Tracking**

- DPH will provide those administering vaccine a data collection form to use to collect the required data fields for each person receiving H1N1 vaccine. It will also capture those not vaccinated because of contraindications.
- Given the large volume of vaccinations anticipated, each vaccinator location will collect the required data and forward the data collection forms to DPH or other designated locations for data entry. The method of form transmission will be determined as best suits each location's needs, and may include: email, courier, fax, pick up, etc.4
- Data will be entered into the Maven software application (DPH's disease surveillance and tracking application) either by direct manual entry or by using scanners and OCR software from scan forms to directly populate data fields into Maven.
- Maven will be used to generate reports, including aggregate reports required by CDC. Maven can be used to generate a file for upload into the CDC's Countermeasures Response Administration (CRA) application using the designated xml format.
- Critical and minimal data elements that will be collected and transmitted to CDC will be identified as required and may include:
  - Vaccine type (e.g., pre-pandemic, pandemic)
  - Date of administration
  - Age group
  - Dose number (1<sup>st</sup>, 2<sup>nd</sup>)
  - Zip code (or Town, which can be assigned to a county for federal reporting)
  - Other information including priority groups as needed
- All vaccine administrators will be required to use the designated data collection forms and report on a schedule determined by DPH during the H1N1 vaccination campaign.
- Data collected on vaccine administered may be used to assist DPH in vaccine inventory management as needed.

**K. Adverse Events Monitoring**

- DPH has identified a Vaccine Safety Coordinator and back up staff that will be assigned to this role from the DPH Immunizations Program.
- DPH will implement active surveillance for cases of Guillain-Barre syndrome (GBS).
- Following the implementation of vaccination against novel H1N1, the Connecticut Emerging Infections Program will contact our 31 acute care hospitals on a weekly basis to determine if there were any admissions for GBS.
- DPH will also attempt to contact neurologists on a regular basis to ask if they have any patients recently diagnosed with GBS. EIP staff will review hospital charts to verify diagnosis and vaccination status, which may also require contact with the provider or the state-maintained H1N1 vaccination database.
- Vaccine safety will be monitored through the Vaccine Adverse Event Reporting System (VAERS). The Immunization Program monitors vaccine safety by ensuring that health care providers report suspected adverse events following vaccination through VAERS.
- DPH will provide all vaccination sites a copy of state policies on VAERS reporting, copies of the VAERS reporting form, instructions on which adverse events must be reported and which can be reported, and instructions on completing and submitting the form.
- Vaccine recipients will be passively monitored for adverse reactions to the vaccine. They will receive instruction on identifying and seeking care for adverse reactions.
- Vaccinators will be responsible for examination and care of persons with adverse events that occur immediately after vaccination (such as anaphylactic reactions).
- Each health care provider and local health jurisdiction that provides immunizations is required to provide the individual and/or parent/guardian information for reporting possible adverse reactions following administration. This includes the practice telephone number as well as the vaccine information statement (VIS) for the specific vaccine being administered.
- Reported vaccine reactions meeting adverse event criteria are to be submitted by all healthcare providers to the state Immunization Program on the Vaccine Adverse Event Reporting System (VAERS) form within 10 days of receipt of vaccine.
- Adverse events related to the vaccine may be made a reportable condition for the duration of the pandemic.
- DPH will use VAERS to report and investigate adverse events following vaccination with a H1N1 influenza vaccine.
- DPH will review existing policies for vaccine adverse event reporting and follow-up to ensure timeliness of reporting and will work with private provider

organizations and mass immunizers to report all events to the state coordinator to minimize duplicate reporting of events to VAERS.

- Adverse events will also be monitored by CDC through CDC's Vaccine Safety Datalink, and Clinical Immunization Safety Assessment (CISA) network.

#### **IV. ROLES AND RESPONSIBILITIES**

- In general, roles and responsibilities are:
  - Intended to clarify which activities will be performed by the state, local and community health partners through a coordinated H1N1 Influenza Vaccine Distribution Response.
  - Consistent with Connecticut General Statutes for a non-emergency coordinated response.
  - Consistent with federal guidance, with the common overarching goals of reducing the impact of the pandemic on the health of Connecticut's citizens and minimizing the disruption to society and the economy.
- The following roles and responsibilities are either additional or are listed for purposes of reinforcing details:

##### **A. DPH**

- Oversees the procurement of the H1N1 vaccine as it is made available by the manufacturers over several months, for distribution through multiple phases as the situation unfolds.
- Coordinates the distribution of the H1N1 vaccine through established systems for the vendors to transport to the appropriate community services providers (i.e., hospitals, health care providers, or local health departments) in accordance with the CDC guidance to facilitate access for the specified priority groups.
- Monitors and provides recommendations for the administration of vaccine to the priority groups in accordance with CDC recommendations.
- The following agency programs will have particularly relevant responsibilities:
  - Immunization Program collaborates with the Communications Office regarding the status of the supply and distribution plan for the H1N1 Influenza Vaccine.
  - Communications – prepare and distribute information for the public and responders.
  - IT Section works with Immunization and Communications to provide needed informatics support
- Monitor and report vaccination distribution, tracking, inventory and adverse events data to CDC.

**B. Mass Dispensing Areas (MDAs)**

- ❑ Each MDA and the respective local health departments/districts within each area should have an H1N1 Influenza Distribution Plan as a component of its pandemic influenza vaccination plan, which should be consistent with the state plan. This plan should specify methods consistent with the options outlined in this plan for use of the anticipated allocation of vaccine to the priority populations as defined by this state's H1N1 Influenza Vaccine Distribution Plan.
- ❑ MDA leads coordinate, collaborate and communicate with the local health departments/districts and community health care providers for their respective area to develop H1N1 Influenza Distribution Plan in accordance with the state's plan as it evolves.
- ❑ MDA leads will collaborate and communicate with DPH regarding the H1N1 Influenza Distribution Plan for their respective area, which should identify how administration of vaccine to prioritized target populations is to be accomplished in a timely manner.
- ❑ Upon activation, store, allocate, secure and monitor the use of vaccine distributed to the MDA.
- ❑ Distribute the proportion of the state's allocations of the H1N1 Influenza Vaccine in a manner consistent with the state vaccine operations plan and the MDA's own plan.
- ❑ Follow the state's instructions on which dispensing strategy to employ as the event evolves.
- ❑ Communicate with staff and volunteers on the rationale for priority groups and sub-groups, and the process for defining priority groups to for vaccination. Use Incident Command Structure (ICS) and established communication channels to communicate with prioritized first responders and infrastructure personnel.
- ❑ As consistent with local public health emergency plans, consider use of hotlines and websites to inform the public when various groups are prioritized for vaccination, and where to go to get vaccinated.
- ❑ Vaccinate individuals consistent with prioritized groups as listed in this state vaccine operations plan (attachment B & C – pages 18-19).
- ❑ Use DPH specified data collection forms and return forms as required to DPH for processing.
- ❑ Monitor vaccine-related adverse events and report on these according to the state and federal guidelines.
- ❑ In accordance with changes in DPH instructions, prepare and return unused vaccine immediately when requested.

**C. Community Healthcare Providers (i.e., pediatricians, community health centers, school based health centers, Visiting Nurse Associations [VNAs])**

- Vaccination sites will maintain cold chain, security, and record keeping in accordance with this plan and any further instructions from DPH.
- Inform their patients about the status of the vaccination campaign and the rationale for prioritization in accordance with DPH guidance.
- Vaccinate individuals consistent with prioritized groups as listed in this state vaccine operations plan and recommendations as the situation evolves (attachment B & C – pages 18-19).
- Report on vaccination in their practice per instructions from the DPH.
- Use DPH specified data collection forms and return forms as required to DPH for processing.
- Follow and comply with state instructions on the monitoring and reporting of adverse events, which may be associated with vaccination.
- Return vaccine to the DPH immediately when requested.

#### **D. Hospitals**

- Have a H1N1 Influenza Vaccine administration plan as a component of its Pandemic Influenza response plan consistent with this state plan.
- Store, allocate, secure, and monitor the use of the vaccine distributed to the hospital, as vaccine is made available.
- Administer vaccine to priority groups among staff in accordance with this plan and state guidelines pursuant to this plan. Communicate with staff the rationale for target groups and priority sub-groups, and the process for defining priority groups to be vaccinated.
- Use DPH specified data collection forms and return forms as required to DPH for processing.
- Monitor vaccine-related adverse events and report on these according to state and federal guidelines.
- Prepare and return any unused vaccine when requested in accordance with DPH instructions.

#### **E. Other Mass Vaccinators**

- Mass vaccinators provide on-site immunization clinics and health screening at retailers such as CVS, Target, Rite Aid, Costco and other retail grocery/pharmacy chains.
- Mass vaccinators may also provide immunization clinics in corporations, senior living communities, physician offices and schools.
- Mass vaccinators work with community organizations to provide resources needed within the timeframe specified.
- Mass vaccinators can supply staff to supplement existing immunization plans dependent on need.
- Vaccination sites utilizing mass vaccinators will maintain cold chain, security, and record keeping in accordance with this plan and further instructions from DPH.

- If mass vaccinators are contracted for services within a MDA, they:
  - Shall distribute a proportion of the state's allocations of the H1N1 Influenza Vaccine in a manner consistent with the state vaccine operations plan and the MDA's own plan.
  - Communicate with mass vaccinator's staff on the rationale for priority groups and sub-groups, and the process for defining priority groups to access vaccine.
  - Inform their patients about the status of the vaccination campaign and the rationale for prioritization in accordance with DPH guidance.
  - Vaccinate individuals consistent with prioritized groups as listed in this state vaccine operations plan and recommendations as the situation evolves (attachment B & C – pages 18-19).
  - Report on vaccination data in the setting used by the mass vaccinator per instructions from the DPH and in coordination with the MDA lead.
  - Use DPH specified data collection forms and return forms as required to DPH for processing.
  - Follow and comply with state instructions on the monitoring and reporting of adverse events, which may be associated with vaccination.
  - Return vaccine to the DPH immediately when requested.

## **V. PLANNING SCENARIOS TO TARGET HIGH-PRIORITY POPULATIONS FOR VACCINATION**

Based on the time vaccine becomes available and distribution begins, planning scenarios to target high priority populations include the following assumptions:

- Severity of illness is unchanged from what has already been observed.
- Risk groups affected by this virus do not change significantly.
- Adequate supplies of vaccine can be produced
- No major antigenic changes are evident that would signal the lack of likely efficacy of the vaccines being produced.

The following planning scenarios that have been recommended by the CDC Advisory Committee on Immunization Practices (ACIP) as of July 29, 2009 are based on vaccine supply.

If there is a sufficient supply of vaccine initially, vaccination efforts should focus on as many people as possible in the following target groups:

- pregnant women,
- people who live with or care for children younger than 6 months of age,
- health care and emergency services personnel,

- persons between the ages of 6 months through 24 years of age, and
- people from ages 25 through 64 years who are at higher risk for novel H1N1 because of chronic health disorders or compromised immune systems.

If the initial supply of vaccine available is in limited quantities. The ACIP committee recommends that the following groups receive vaccine before others:

- pregnant women,
- people who live with or care for children younger than 6 months of age,
- health care and emergency services personnel with direct patient contact,
- children 6 months through 4 years of age, and
- children 5 through 18 years of age who have chronic medical conditions.

Once the demand for vaccine for the prioritized groups listed above has been met, the ACIP recommends expanding vaccination efforts to include everyone from ages 25 through 64 years. Current studies indicate the risk for infection among persons age 65 or older is less than the risk for younger age groups. Once vaccine supply and demand for vaccine among younger age groups has been met, vaccination efforts can be expanded again to include people over the age of 65.

## **VI. PLAN DEVELOPMENT AND MAINTENANCE**

- This plan will be updated annually or more often as conditions change, as the science advances, as countermeasures improve, and as planning evolves.
- This H1N1 Vaccine Distribution Response Plan will be publicized through posting of excerpts on the Connecticut FluWatch website <http://www.ct.gov/ctfluwatch>.

## **VII. ATTACHMENTS**

8/11/2009

14

**A. Table 1: Populations to be vaccinated and resources to perform vaccination**

Category	Target Group	Estimated Number*	Vaccinated By**	Vaccination sites
Healthcare and community support services	Public Health Personnel	3,310	Mass Dispensing/Local Health/VNAs/Maxim	Local Health Departments/Mass Dispensing sites
	Inpatient healthcare providers	75,000	Hospitals will be given a supply of vaccine to provide vaccinations for each employee that wants to be vaccinated	Hospitals
	Outpatient, Community Health Center and Home Health Providers	22,000	VNAS/Maxim/Local Health/CHC	Agency homes, local health departments
	Healthcare providers in LTCFs	8,800	Long Term Care Providers	Long Term Care Facilities
Critical Infrastructure	Emergency Medical Service Personnel	22,000	PODS/Mass Dispensing group Maxim (private groups) VNAs, local health departments	Mass Dispensing locations, schools, EMT agencies
	Law Enforcement personnel			
	Fire Service Personnel	550	VNAs/Maxim	Local identified site, Legislative Office Building
General Population	Pregnant women	36,000	CHC, OB/GYN, Private providers	Private Practitioners' office***/Community health centers
	Infants & Toddlers 6-35 Mo. old	113,310	Pediatric provider groups, CHCs	Private Practitioners' offices, CHCs, Daycare facilities
Homeland Security	Essential support & sustainment personnel	7,150	Mass Dispensing/Maxim/VNAs/Local Health	DEMHS identified Locations
	National Guard personnel	5,500	Medical National Guard providers	National Guard bases
Healthcare and community support	Community support and emergency mgmt.	6,600	Mass Dispensing, LHD, Maxim, VNAs	Local Agency sites

8/11/2009

15

Connecticut Department of Public Health  
H1N1 Vaccine Distribution Response Plan

8/11/09

support				
Critical Infrastructure	Electricity sector personnel Natural gas personnel Communications personnel Water Sector personnel Critical government personnel	20,900-48,400	Mass Dispensing/LHD/Maxim/VNA	Mass Dispensing sites (schools/local meeting areas)
Homeland Security	Other active duty & essential support	16,500	Military (own supply)	Military locations
Healthcare and Community Support	Other important healthcare personnel	5,500	Private Providers/VNA/Maxim/Mass Dispensing/CHC	Local Provider offices, community sites
Critical Infrastructure	Transportation sector personnel Food and agriculture sector personnel Banking and finance personnel Pharmaceutical sector personnel Chemical sector personnel Oil sector personnel Postal and shipping personnel Other important government personnel Funeral directors and embalmers	15,400 to 38,500	Mass Dispensing/VNAs/Maxim/Local Health	Local identified Mass Vaccination sites(schools. Arenas)
General Population	Household contacts of infants < 6 mo	60,000	Private Providers/Local Health Departments/CHC	Private Providers Offices Community Health centers
	Children 3-18 yrs with high risk cond.	71,500	Pediatric Providers/SBHC/schools	Schools, Day Care Centers, Private Practitioners Offices

8/11/2009

16

Connecticut Department of Public Health  
H1N1 Vaccine Distribution Response Plan

8/11/09

General Population	Children 3-18yrs without high risk	643,500	SBHC/Schools/Local Health Departments/Maxim	Day Care Facilities Schools Community Health Centers
General Population	Persons 19-64 with high risk cond.	396,000	Private Health Care Providers Mass Dispensing/VNAs/Maxim/Local Health Departments	Local Mass Vaccination sites (schools, large public buildings) Private Practitioner offices
General Population	Persons > 65 yrs old	418,000	Mass Dispensing/VNAs/Maxim/Local Health Departments	Local Mass Vaccination sites (schools, large public buildings)
General Population	Healthy adults 19-64 yrs old	1,339,800	Mass Dispensing/VNAs/Maxim/Local Health Departments	Local Mass Vaccination sites (schools, large public buildings)

Based on numbers 1.1% US population

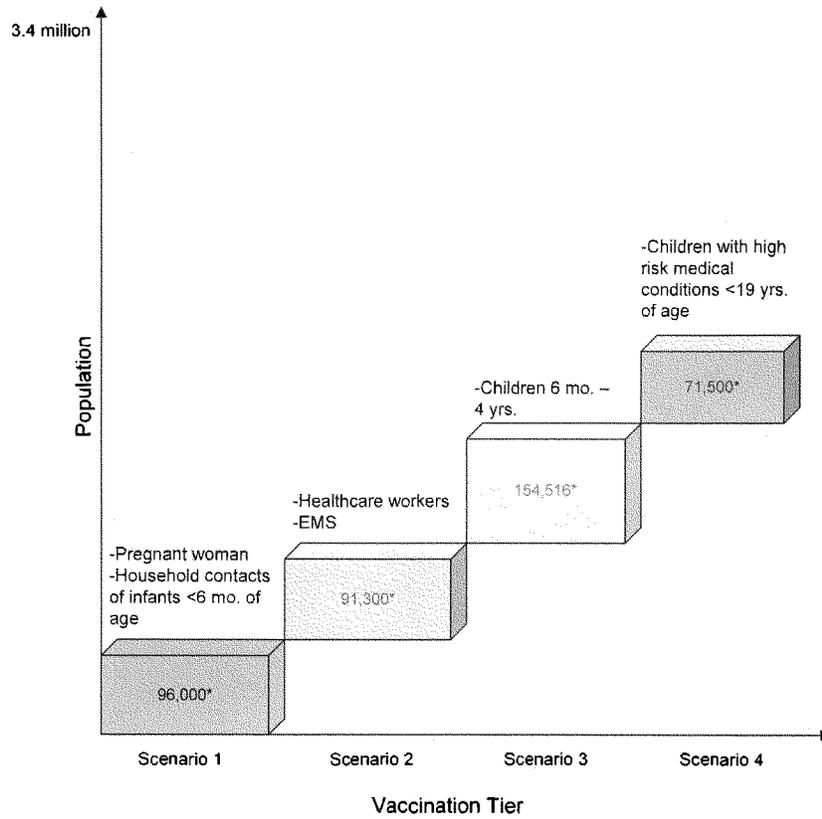
\*\* Follow state instructions on which dispensing strategy to employ, including prioritization and definitions of target groups for vaccination.

\*\*\* Local Practitioners could work together to regionalize vaccination sites. Several practitioners would use offices to vaccinate multiple practitioners' patients

8/11/2009

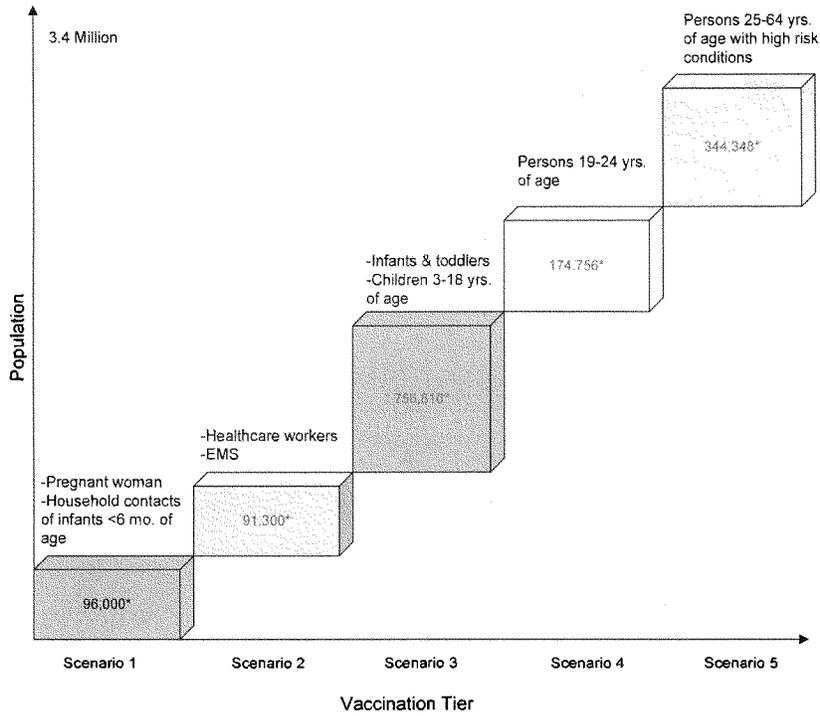
17

**B. Figure 1: Priority Populations for Vaccination Based on Limited Supply According to CDC ACIP Sub-Group Planning Scenarios.**



\*Population group estimates

**C. Figure 2: Priority Populations for Vaccination Based on Adequate Supply According to CDC ACIP Sub-Group Planning Scenarios.\***

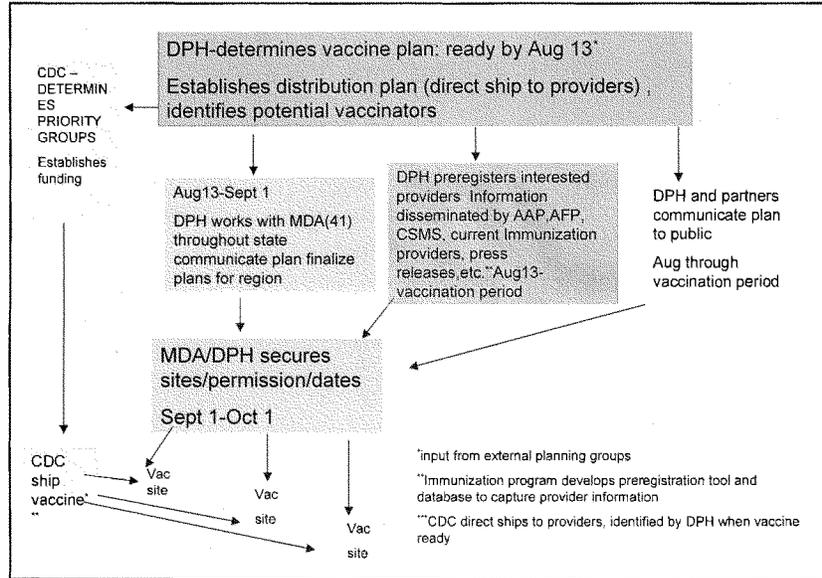


\*Population group estimates

\*When vaccine availability is sufficient at the local level to routinely vaccinate initial target populations, in consultation with State and local health departments, vaccination against H1N1 is recommended for all healthy adults 25-64 yrs of age.

\*Vaccination is recommended for persons 65 years or older once the demand for vaccination of younger age groups is met.

**D. Figure 3: CT Department of Public Health H1N1 Vaccine Delivery Schematic**



TESTIMONY OF PETER J. BOYNTON  
COMMISSIONER  
STATE OF CONNECTICUT  
DEPARTMENT OF EMERGENCY MANAGEMENT AND  
HOMELAND SECURITY

BEFORE THE

COMMITTEE ON HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

UNITED STATES SENATE

SEPTEMBER 21, 2009

HARTFORD, CONNECTICUT

**TESTIMONY BEFORE SENATE COMMITTEE ON HOMELAND  
SECURITY AND GOVERNMENTAL AFFAIRS**

**OPENING COMMENTS**

Senator Lieberman and Senator Collins, members of the Committee, good morning and thank you for inviting me here today. My name is Peter Boynton and I am the Commissioner of the Connecticut Department of Emergency Management and Homeland Security. I am here to talk to you about the ongoing planning and preparedness work being done to ready the State of Connecticut for a potential H1N1 Flu outbreak this Fall. There are three themes that I would like to emphasize today: first, planning and preparedness; second, information sharing and outreach; and third, collaboration.

As a preliminary matter, I will defer to my colleague from the Connecticut Department of Public Health, Dr. Matthew Cartter, on the current status of the H1N1 outbreak in Connecticut and the surveillance efforts that the public health community is conducting.

The Connecticut Department of Emergency Management and Homeland Security (DEMHS) regularly works very closely with the Connecticut Department of Public Health (DPH), but particularly during a public health event such as the H1N1 outbreak. This leads to my first theme, the importance of planning and preparedness, because both agencies, along with many other partners, are working to plan and prepare for an H1N1 outbreak in Connecticut. The State of Connecticut has a Pandemic Influenza Response Plan and an H1N1 Vaccine Distribution Response Plan, both authored by DPH, which is the state agency designated by Governor M. Jodi Rell to lead the H1N1 Response in Connecticut.

In addition to the statewide planning that has taken place, the State of Connecticut has taken many steps to ensure continuity of operations of critical state government functions. Beginning as early as December of 2005, Governor Rell directed state agencies to engage in pandemic Continuity of Operations planning (COOP). Led by the state Department of Administrative Services, state agencies participated in COOP training, which culminated in the institution of COOP plans for 55 state agencies.

Each state agency identified its essential functions, and created a pandemic COOP Incident Management Team. With this foundation already in place, this past August, the Governor directed state agencies to review their plans and convene their Incident Management Teams to prepare for H1N1-related issues.

In its emergency management role, the task for DEMHS is not only to maintain its own essential functions, but to assist others at the state and local levels to maintain their operations. The role of DEMHS is to coordinate, as we do in every emergency, but in a pandemic incident, the coordination or incident management role is a bit different. Rather than dealing with a quickly-occurring “acute” incident such as a hurricane or tornado, we must be ready to deal with a long-term or “chronic” incident.

DEMHS has established three activation levels—monitoring, partial activation and full activation. We are currently in the monitoring mode, prior to any activation of the State Emergency Operations Center. A key component of the monitoring mode is the subject of my second theme-- information review and sharing, and outreach to all our partners as well as to the community at large.

DEMHS, DPH, and the state Department of Administrative Services (DAS) are working with the Governor’s Office to provide accurate, current and consistent information on the H1N1 situation.

The Governor held three H1N1 Summits; the first for schools Grades K through 12; the second for higher education and residential schools; and the third for municipal officials. These Summits provided up-to-date information on H1N1 and state planning efforts from subject matter experts. All were well attended, received media coverage, and, as an additional way to reach out to the general public, were broadcast on the Connecticut Television Network (or CTN), Connecticut Government’s cable channel which is available throughout the state.

The Governor has made several Public Service Announcements which have already begun to air on television and radio. The first PSA emphasized the importance of personal preparedness. The Governor’s message also directs Connecticut residents to go to the Connecticut Flu Watch web site [[www.ct.gov/ctfluwatch](http://www.ct.gov/ctfluwatch)] for more information. This web site is a central

web portal not only for the public but also for schools, universities, health care providers, and businesses.

Beginning with the first outbreak of H1N1 in the Spring of this year, information sharing with our partners such as public and private health directors and providers, emergency management directors and municipal chief executive officers, school officials and state agencies was accomplished through a series of regular telephone conferences with DEMHS and DPH. Teleconferences are being used again this Fall as well.

DEMHS is also sharing information on the H1N1 incident through a computer system known as Web EOC. Web EOC is a real time web-based situational awareness tool for communicating with federal, state and local partners. DEMHS uses Web EOC as a tool to communicate particularly with Emergency Management Directors and other officials at the local level. Over 650 individuals have been trained in Web EOC, from 150 towns across the state, as well as state agency representatives. In addition to traditional email messaging, this tool gives us the opportunity to spread information quickly across the state for a common operational picture.

My third theme—collaboration—leverages the success of all other efforts. I have already described many of the collaborative activities that have taken place, and continue to take place, at the state and local levels in Connecticut, including teleconferences, Web EOC, flu summits and public education.

At the local level, collaboration is encouraged in a variety of ways. For example, each municipality is required by state statute to have an all-hazards local emergency operations plan, which must be reviewed annually, not only by the local emergency management director but by the local chief executive officer and the Commissioner of DEMHS as well. An all-hazards plan delineates the roles and responsibilities at the local level for any emergency. The State of Connecticut also passed legislation in 2007 creating an Intrastate Mutual Aid System to allow each municipality to assist any other municipality that has declared a state of emergency.

In addition, the State of Connecticut collaborates with other states, and our federal partners. For example, this past July, Governor Rell joined five other Governors and representatives from DEMHS and DPH in participating in a National Flu Summit to discuss the springtime H1N1 outbreak and planning for the fall flu season.

Finally, on August 20, 2009, the Northeast States Emergency Consortium held its quarterly meeting of state emergency management directors, chaired by the Connecticut Director of Emergency Management, William Hackett, in Brattleboro, Vermont. The August meeting was dedicated to H1N1 issues, and included not only the emergency management directors from each of the New England states and the State of New York, but also state public health directors, FEMA Region 1 Acting Administrator Paul Ford, Admiral George Naccara, DHS Regional Coordination Team Lead, Admiral Michael Milner, Senior Federal Official for HHS in the Northeast, as well as Associate Director for Emergency Response at the CDC, Admiral Scott Deitchman.

These opportunities, at the local, state, regional and national levels, for all to meet and exchange ideas, best practices, and concerns in anticipation of a potential crisis enhances the collaborative effort -- across geographical areas, across disciplines and across levels of government -- which is essential during an actual crisis.

Thank you to the Committee for this opportunity to address you, and I would be glad to answer any questions you may have.

**H1N1 Flu: Protecting Our Communities****Challenge to Hospitals**

Stephen G. Jones, MD  
 Yale New Haven Health System  
 Center for Emergency Preparedness and Disaster Response

It has been said that "the most *predictable* thing about Pandemic flu is its *unpredictability*."

The emergence of pandemic H1N1 flu this past spring, while providing a real and for the most part unwelcome challenge to our health care system, also offers a unique opportunity to evaluate and assess our preparedness models and strategies.

Pandemic flu is a relatively rare event but significant in that it challenges all levels of society and does so on a global scale. Prior to this new pandemic, there have been just 10 pandemics over the past 300 years. It has been over 40 years since the world last saw such an event and over 90 years since the worst pandemic of history. The 1918 Spanish flu killed over 50 million people, 675,000 in the United States alone.

The impact of a pandemic on society can be defined for the most part by two simple features of any influenza strain. They are:

- 1) Infectivity (how contagious)
- 2) Virulence (how severe)

Although the present H1N1 pandemic strain is a descendent of the 1918 Spanish flu (also an H1N1 flu) it is significantly less virulent producing relatively mild symptoms in the majority of those affected. It is import to bear in mind that this pandemic which is presently in the process of testing our systems is far from a worst case scenario. As such, any issues or deficiencies it exposes would be significantly magnified with a more virulent strain.

The challenges facing the health care delivery network in the setting of a pandemic outbreak are daunting. Under normal circumstances, absent of a pandemic event, the following facts hold true:

- On any given day, hospitals are running at near capacity
- Intensive Care Units and monitored beds are almost always full
- There are about 110,000 ventilators in the US and on an average day 75,000 are in use; during normal "seasonal" flu about 100,000 are in use
- Emergency departments are literally clogged with ever increasing numbers of patients seeking care; many patients are kept in the ED sometimes for hours or days while waiting for a bed to open up in the hospital
- Staffing, particularly nursing, is strained (the recent economic downturn has magnified this problem as hospitals have had to reduce staffing just to survive)
- Due to a "just-in-time" environment, hospitals are only able to maintain limited supplies on site including pharmaceuticals, blood products, general medical supplies (i.e. syringes, linens, face masks, etc.), and even food and water

In short, hospitals have limited capacity to "flex up" from their normal baseline daily operations.

**Pandemic Situation**

The most significant challenge facing hospitals with the current circulating strain of Pandemic H1N1 flu is the capacity to respond to the increased burden it places on an already strained healthcare system. This "surge" cuts across all areas of the healthcare delivery network. It is estimated that at its peak 30 – 50% of the general population will be afflicted with the flu. At the same time, it is important to remember that the same percentage of health care workers will also be affected. This "perfect storm" of increasing numbers of people requiring medical care with decreasing numbers of healthcare workers able to provide them speaks to one of our most challenging problems. As outlined above, hospitals, even absent a pandemic, are operating at near capacity and have little margin to absorb such a large increase in people seeking care.

Our Yale New Haven Health System hospitals experience earlier this year with the emergence of this H1N1 strain demonstrated other aspects of this problem. We found the following:

- Private physicians in the community surrounding the hospital referred many of their patients directly to the hospital for both testing and care
- Our Emergency Departments saw a significant increase in the number of patients presenting with mild symptoms (sometimes just the sniffles) who otherwise would not have come but were "afraid" it was pandemic flu ("worried well"). The most significant increases were seen in the pediatric population.
- Visits to our outpatient centers were significantly increased for the same reasons
- Urgent care visits and "walk-ins" increased dramatically
- Logistical challenges arose in regards to isolating patients with suspected flu from other non-infected patients
- Respiratory therapists and lab workers worked overtime just meeting the need for testing
- CDC and state recommendations regarding testing were not always consistent with one another
- Our infectious disease team was stretched with increasing demand place on them in regards to patient care, hospital planning, education, and media
- We continued to see the flu into the summer (almost unheard of)

It is instructive to remember this was occurring when the flu was not widespread and with the hospital fully staffed and operating at near capacity. The scenario clearly would be (and likely will be) different when the pandemic impacts the community at its peak.

Another challenge was getting information out to the community, including physicians, regarding updates and recommendations. Each of our hospitals established a pandemic flu hotline that was updated regularly as was our website.

**Other considerations:**

- What happens in other sectors of the community in regards to the pandemic influenza can greatly impact the health care system. For instance, when schools/day care centers close it is likely that at least one parent will be pulled from the work force to provide child care. This again would include healthcare providers.
- Pandemic influenza is not a local event; communities and hospitals will not be able to tap into other surrounding hospitals or healthcare delivery organizations for support

- Supply chains may be compromised as providers and transporters (i.e. truckers) are affected; again, due to the "just-in-time" environment in which we function, hospitals maintain only limited supplies on site
- The availability and method of distribution of both vaccine and anti-virals in conjunction with determining who should receive such products, and when, is yet another challenge
- We have seen significant and welcome funding provided to states to address pandemic preparedness. However, the bulk of this federal funding does not reach the local level where hospitals truly need it. In Connecticut, hospitals will receive about 20% of this funding, in most other states hospitals will receive less.

In summary, the efforts of the Federal and State government in conjunction with local communities to prepare for and respond to pandemic influenza are commendable. In addition, the Yale New Haven Health Systems Center for Emergency Preparedness and Disaster Response have endeavored to provide its system hospitals, and other hospitals throughout the state and surrounding communities, the highest level of available emergency and public health preparedness services. Despite these efforts significant challenges remain.

We would offer the following recommendations for consideration:

1. Increase the focus on helping hospital build into their systems the capabilities to safely respond and absorb "surge" conditions such as pandemic influenza
2. Increase the allocation of funding for hospitals to meet increased costs of managing pandemic influenza events including staffing, overtime, training, pharmaceuticals, personal protective equipment and supplies.
3. Improve coordination of the State with the CDC in providing hospitals guidelines and recommendations in a timely manner
4. Encourage all health workers to receive their influenza vaccines voluntarily to maintain those providers in the work force during a pandemic influenza outbreak and more importantly to protect the patients they care for
5. Understand that pandemic influenza is not necessarily seasonal and that readiness must be maintained throughout the entire calendar year
6. Support and reaffirm efforts to educate the general population on the importance of *prevention* (i.e. hand washing, alcohol gels, vaccines, etc.)
7. Support and reaffirm efforts to educate the general population on the importance of *preparedness* (i.e. having basics supplies, medications and other necessary items stored at home as well as advanced planning for issues such as child care, etc.)
8. Support and reaffirm efforts to educate the general population on the importance of *recognition* of the signs and symptoms and what steps should be taken to receive care and treatment
9. Implement a comprehensive review and debriefing on a state level at the conclusion of this pandemic influenza event.

As stated earlier, "the most predictable thing about this flu is its unpredictability". There is no doubt that the extraordinary efforts we have already seen, and continue to see, from so many will serve to mitigate this present challenge, and, as we pass through it, enlighten us for the future.

Thank you.

Prepared Statement of Julie A. Polansky  
Parent  
Vernon Public Schools  
September 21, 2009

Senator Lieberman,

In April of 2009, shortly after spring vacation, Vernon Public Schools closed for two days due to a suspected case of the H1N1 influenza virus. Most parents, including myself, learned of the closure via local television news outlets. The school system did not notify parents through email or phone calls; however a notice was posted on the Vernon Public Schools website. Since this was an unexpected closure (i.e., not a snow day), I did hear of a few parents who had not watched the local news and were unaware of the situation. Having and utilizing an emergency notification system would have greatly helped facilitate communication to parents.

Additionally, communication regarding the reasoning for the closure was vague. Parents were aware that the closure was due to H1N1 but initially did not receive information about the number of suspected cases or the location (school) of the potentially infected individual(s). This lack of information caused unnecessary speculation and rumor on the part of parents in the community.

Guidelines for the community of Vernon were also lacking. Due to the closure of schools, little league practices and games were cancelled. In fact, on the day that Administration closed the schools for the following two days (which was announced via the news outlets at approximately 4:30 p.m.), parents and children were turned away when they arrived for practices at the various little league fields.

In the case of Vernon, the suspected case that caused the closure turned out to be influenza, but not H1N1. I understand Administrations cautious decision in the interest of the children; however, since it was merely one suspected case, it may have been adequate to either wait for the results of testing or close the one impacted school, not the entire district. I would also like to point out that I believe the closure of schools is truly warranted if a significant number of children and/or staff become infected in one location.

The impact the two day closure of school had on me as a working parent was relatively significant. Luckily, I work locally and have a flexible schedule but I was forced to rearrange my work day and make arrangements with friends for daycare. Many other parents simply utilized daycare facilities for their elementary aged children. So my question becomes, does the closure of schools actually help to stop the spread of the flu virus – what is the difference between children being together at school versus at a daycare facility? I have no problem taking time off of work and keeping my children home if they are sick; however, if schools are closed and my children are healthy, I will continue to allow them to play with their friends.

Subsequent to the closure of school, the system distributed the State guidelines for ill children. These guidelines were clear and reasonable.

Guidance for School Administration regarding the make-up of H1N1 days appears to me to be vague. In Vernon, initially, parents were informed that the H1N1 days would need to be made up at the end of the school year. This would have made the last day of the 2008-2009 school year for Vernon, June 30, 2009. This situation caused issues for a number of parents and staff since it was 4<sup>th</sup> of July week. Subsequently, the Board of Education reversed the decision and through negotiation and coordination with the teacher's union, the students did not need to make up the H1N1 closure days. This situation caused confusion and frustration for all involved. Some guidelines or guidance from the State on whether districts need to make up influenza closure days would have been helpful.

My hope for the current school year is for clear communication and careful preparation. I am happy to report that the Vernon Public School Nurses have already distributed a flyer to parents outlining the district's recommendations on how to help stop the spread of flu and other illnesses. This flyer included details on flu symptoms, recommendations on how long children should remain home, information on the vaccine and prevention tips. It was also noted that the nurses are working closely with a local physician and the Department of Public Health to monitor the flu condition and make decisions about the best steps to take concerning schools. I hope the district will continue to provide periodic updates via additional flyers, guest speakers at PTO meetings, and the school websites.

In terms of preparation, I believe it would be prudent for schools to have funding set aside for continuous supplies of antibacterial hand soap and periodic 'extra' cleaning of the buildings. Since most school budgets are extremely lean, I wonder if it is possible to have state or federal funding for these preventive measures.

Guidance from the government is crucial. Guidelines regarding who should get a flu shot, whether sick children should visit their primary care physician, how long a child should remain home after being ill, when and if schools should close, and how community/sports groups or leagues should handle any outbreaks should be readily available to the public.

Thank you for the opportunity to participate in this hearing.

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DEPARTMENT OF PUBLIC HEALTH  
**THE CITY OF WATERBURY**  
CONNECTICUT

Statement of Roseann Wright, RN, RS, MPH  
Director of Public Health  
Waterbury Connecticut  
Before the  
Committee on Homeland Security and Governmental Affairs  
United States Senate  
September 21, 2009

**Opening Statement**

Good Morning Mr. Chairman and members of the Committee. Thank you for this opportunity to testify at today's hearing "H1N1 Flu: Protecting Our Communities". I am Roseann Wright, Director of Public Health for the City of Waterbury, Connecticut. I am here today to share our experiences in Waterbury and how the public health department, school district, and School Nurses dealt with the H1N1 influenza outbreak.

The City of Waterbury is the fifth largest city in the State of Connecticut, 28.9 square miles in size and is home to a population of 107,271. In addition, Waterbury has 18,938 students enrolled in a public school system that is comprised of three (3) high schools, four (4) middle schools, and twenty (20) elementary schools. Six (6) private and parochial elementary schools and two (2) parochial high schools enroll a total of 3,000 students in addition to the public school system student body. Waterbury Public School District's statistical data clearly indicates that ninety-five percent (95%) of Waterbury Public School students are eligible for free and/or reduced lunch. Poverty exceeds 44% in many of Waterbury's low-income census tract districts primarily found in its north end and south end neighborhoods. Increasingly, Waterbury's student households are largely under-to-uninsured and rely on the services of the School Nurse within the School Health Program to act as the student's primary health caregiver.

To support the Waterbury Public, Private and Parochial School Systems, the Waterbury Public Health Department (WPHD) employs three (3) Nursing Supervisors, thirty-nine (39) School Nurses, and twenty (20) Public Health Aides which comprise the School Health Program for this municipality. Located within each public, private, and parochial school there is a School Nurse from the Waterbury Public Health Department, School

Health Program that is on-site for the entire school day. The School Nurse's assignment can be challenging in Waterbury's middle and high schools as those student body populations often exceed 1,200 students.

The goal of the School Health Program is to foster a proactive collaboration with the Waterbury Public School District and Private and Parochial Schools to attain the following objectives: 1) provide medical interventions for students requiring first aid or minor medical evaluation in the school health rooms, 2) creation of a comprehensive school health program that fosters health education tailored to age-related target populations within the student body and student households, 3) initiate comprehensive medical screenings, health assessments, childhood immunizations, sports physicals, and medication administration, and 4) tailor individual health care plans for students with medical risks and/or disabilities.

The following is a brief synopsis of the Waterbury Public Health Department's compilation of School Nursing interventions recorded for the 2008 -2009 school year:

Student encounters:	
Illness/first aid visits:	175,052
911 Call initiated:	130
Medications administered:	36,142
Special procedures:	15,069
School children immunized:	482
Total medical interventions:	226,263

I, as the Director of Public Health, cannot place enough stress on the importance of the School Nurse in the academic environment in terms of identifying, assessing and tracking communicable diseases within the school population. Identification of a communicable disease outbreak by the School Nurse within the academic environment is a potential indicator for a communicable outbreak within our community. In the event of any communicable disease, in this case H1N1, the School Nurse is an essential element of the public health team. The School Nurse is often the first staff member to identify common signs and symptoms of a communicable disease and alert the Public Health administrators. During the pandemic of H1N1, the Waterbury School Nurses are integral in conducting surveillance in school populations. The School Nurse is also delegated the responsibility of identifying students who need testing and medical treatment and subsequently report cases to their Nursing Supervisor.

#### **Spring 2009 H1N1 Influenza Outbreak**

Early in the spring of 2009, area hospitals and private practitioners were screening for H1N1 and receiving positive test results for the H1N1 influenza virus. During this time, a number of confirmed H1N1 cases were reported with increasing frequency, prompting the WPHD to proactively educate the public to try and minimize the spread of H1N1. WPHD set into motion a mass education campaign that was multimedia in its effect. Internally, the WPHD planned for the possibility of H1N1 to be the next pandemic and how could we protect public health personnel – such as our School Nurses and Public

Health Aides-- from contracting H1N1. We reviewed the incidences of absentees within the student body to determine if outbreaks were occurring in the academic environment. In addition, daily communications between the School Nurses and their immediate School Nursing Supervisors demonstrated a significant increase in the frequency of influenza-like illnesses within the student population. WPHD also sent Sanitarians to every school to inspect all bathrooms ensuring there were plentiful supplies of hand soap, paper towels and that water temperatures were within 100 - 115 degrees Fahrenheit. The WPHD sent bilingual communications to parents of school-aged children through the Waterbury School Superintendent's Office that addressed the symptoms of H1N1, offered Center for Disease Control and Prevention (CDC) prevention tips, respiratory etiquette and information regarding Swine Flu. School personnel also instituted new protocols for cleaning all school surfaces and high traffic areas.

WPHD conducted staff meetings with School Nurses, Sanitarians, and other professional staff. We urged all personnel to take special precautions and to be conscientious with hand washing and respiratory etiquette. Supervisors provided ongoing guidance and support to all staff. An important training tool utilized by this administration was a tabletop drill that was conducted in January 2009 for school nurses regarding their roles and responsibilities during a pandemic. This drill was an opportunity for the nurses to immerse themselves in a scenario that would test their responses if a pandemic were to emerge. This training would prove useful in the coming months.

The School Nurses and their immediate Nursing Supervisor became our sentinel for the community's health; thus we established new reporting procedures for reporting of possible H1N1 cases in the schools. Communications between the Mayor's Office and Director of Public Health occurred daily. Health Department administrators participated in weekly conference calls with the Connecticut Department of Public Health (CTDPH). There were increased communications between the WPHD, the Superintendent of Schools and all Private and Parochial Principals that addressed confirmed cases of H1N1 in their schools. At that point, the CDC was issuing early guidance which was incorporated into all of our protocols.

The City of Waterbury's first public incident occurred during a local field trip on April 30, 2009, when one of the elementary school students stated that she did not feel well and exhibited influenza-like illness. The child indicated to her teacher that she had just returned from spring vacation in Cancun with her family. This single occurrence caused panic and hysteria in mere minutes with school personnel, and parents. As a result, an elementary school was closed for two days by the Superintendent of Schools and every surface of the school and the school buses were sanitized in accordance with CDC guidelines. The WPHD and nursing supervisory staff were inundated by calls from parents and citizens in the community who were demanding further information as to the spread of H1N1 beyond this one incident. WPHD staff noted that this case was epic in nature because it had garnered so much public attention and brought H1N1 to the forefront of local news and community awareness.

The WPHD sent out letters through the Waterbury Public School District to all public school students and shared the contents of the letter with the School Nurses and principals of all parochial and private schools in the City of Waterbury. These communications highlighted prevention tips and respiratory etiquette, as established by the CDC. This was landmark guidance in Waterbury that established a single H1N1 protocol for all School Nurses – regardless of their assignment. The WPHD has one set of H1N1 protocols followed by all of its employees regardless of job site or assignment in order to ensure that a unified message is sent out to every student household in the City of Waterbury so there can be no miscommunication or confusion.

#### **Non-Pharmaceutical Mitigation Interventions**

It is imperative during the school year that the School Nurses practice non-pharmaceutical interventions such as infection control techniques:

- Hand sanitizer has been purchased by the Waterbury Public Health Department and has been placed in all school health rooms and outside of the cafeterias.
- Clorox wipes have been distributed to School Nurses and teachers.
- Pre-k to Grade 3 teachers have been encouraged to take frequent bathroom breaks so that students are washing their hands.
- Encourage all students and staff to stay home when they are ill and to only attend school when they are well.
- Custodians are cleaning surfaces and items that are likely to have frequent hand contact.
- We are paying special attention to our high-risk population which includes pregnant women, medically at-risk children, and adults over the age of 65.

The WPDH implemented our Pandemic Influenza Plan. A component of this plan is for the School Health Program to maintain an accurate emergency contact list for all personnel and community partners. School Nurses are also vertically cross-trained to provide a consistent standard of care throughout the City's health rooms.

As part of Connecticut's Department of Emergency Management and Homeland Security Region 5, the Waterbury Public Health Department meets on a monthly basis with counterparts from health departments and health care entities. These meetings allow members share ideas and develop a coordinated response to an emergency. WPDH Nursing Supervisors also proactively collaborate with regional health supervisors to share and disseminate important information concerning mitigation strategies, lessons learned, and other valuable information which is shared with the School Nurses.

#### **Expectations for 2009 - 2010 School Year**

On August 31<sup>st</sup> the Superintendent of Schools sent out a letter to all parents/guardians that highlighted proper protocols when a child exhibits influenza-like illnesses and what the schools will do to maintain a healthy environment. That letter also mandated that students must stay home until all symptoms are gone AND for 48 hours thereafter

before they can return to school. This letter was shared with all Parochial and Private Principals so the message to parents and students was consistent throughout Waterbury.

In anticipation of the 2009 - 2010 school year, the WPHD developed new policies and procedures to prepare for H1N1 to appear in the student body relatively early in the school year. Those preparations consisted of staff meetings prior to the school year that reinforced the importance of health education including respiratory etiquette, hand washing, staying home when ill, and a review of signs/symptoms and reporting procedures. Pamphlets were distributed to all School Nurses and tracking and data collection tools were developed to monitor those students identified with influenza-like illness such as fever of 100 degrees or more, sore throat, and cough. This new data collection tool will allow the School Nurses to monitor siblings and will determine when a child can return to school per the Superintendent of School's guidance. Identifying influenza-like illnesses will assist the School Nurse if an outbreak is occurring in the school. School Nurses are required to identify students and staff with special medical needs and other medical complications which would potentially put them at higher risk for complications as a result of seasonal influenza and H1N1. When a School Nurse has identified an outbreak in the school, these at-risk students and staff will be notified. This notification allows high-risk students and staff to notify their healthcare provider and seek appropriate medical guidance. Some examples of at-risk populations in school would be pregnant students and staff, staff who are 65 years or older, students and staff with chronic medical conditions.

Monitoring illness in schools is a primary function for the School Nurses in order to identify H1N1 outbreaks as early as possible throughout the public, private and parochial school system. If a School Nurse excludes a child for illness (fever, sore throat, cough) they will assess that student upon his/her return to school which includes a risk assessment of the entire student household. School Nurses will work with WPHD and school administrators by collecting and reporting the number of school aged children and staff who are exhibiting influenza-like symptoms. We continue to prepare our School Nurses by keeping them abreast of any news or new guidelines from the CDC or CT DPH.

School Nurses are the medical professionals in school environments and can offer education to students, staff, and parents about the latest information about H1N1, how to maintain health, as well as mitigating interventions to decrease the spread of infectious agents. This can be accomplished through classroom presentations, fact sheets, newsletters, school web sites, and use of the media. Currently all School Nurses are distributing the *Cover Your Cough* and the *Six Prevention Tips* to all students coming to the School Health Rooms. Last year, 39 School Nurses encountered over 175, 000 students through health room visits. Providing continuous repeated education to this population will help to minimize the impact of the spread of H1N1. This is especially important for school-aged populations since most pandemics usually involve novel strains that result in higher incidence rates among those under 18 years of age due to lack of herd immunity.

**Guidance from Federal and State Governments**

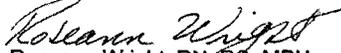
The WPHD is utilizing state and federal guidance documents as a tool to develop specific strategies that are customized to the needs of Waterbury's academic environment. These guidance documents are assisting us to minimize the spread of H1N1 amongst our students and school staff during the 2009 - 2010 school year. The guidance documents provide a variety of tools that Waterbury Public Health Department officials, School Nurses, and school administrators are utilizing based on the conditions found during the spring of 2009.

Although Waterbury is following federal guidelines regarding exclusion of the ill students and staff with influenza-like illness, we have adopted stricter guidelines that enforce exclusion for 48 hours after the resolution of symptoms. The Waterbury Public Health Department has embraced the universal nature of the guidance document because it allows us to incorporate the protocols contained therein to all K-12 public, private, and parochial schools in Waterbury. The federal guidance documents are assisting the School Nurses in minimizing the potential impact and decreasing the risk of exposure to H1N1 while limiting the disruption of day-to-day activities and thus facilitating educational continuity.

Like other urban cities whose populations are multi-cultural, significant linguistic and cultural challenges must be surmounted in order for health authorities to effectively offer prevention and public health protection as we mitigate exposure risk to H1N1 and other communicable diseases. The Waterbury Public Health Department is utilizing the guidance document as one of our tools to minimize the impact of H1N1. Waterbury recognizes we are not alone in the prevention and management of H1N1 and we share the same challenges and burdens as other municipalities across the State of Connecticut and the nation.

In conclusion, as the pandemic continues to increase in intensity, the role of the School Nurse will evolve from the traditional caregiver to also include functions such as health educator and sentinels for the community's health.

Thank you,

  
Roseann Wright, RN, BS, MPH  
Director of Public Health  
Waterbury, Connecticut

Prepared Statement of Daniel Aloï  
Manager, Business Continuity Services  
Aetna, Inc.  
September 21, 2009

Aetna is pleased to be in attendance today to share our plans and experience with the panel. We are members of the Homeland Security Critical Infrastructure Subcommittee on Healthcare and are actively involved with the public and private sector in advancing all preparedness. We are continually learning, as everyone is, and constantly testing our plans. We see no limits on the sharing of information when it comes to the public good and the nation's resilience in a disaster. Aetna occupies over 100 facilities at various sites throughout the country which house a variety of Aetna departments and functions.

To prepare for pandemics, Aetna has developed many recovery or coping strategies to ensure continuity of operations and to keep employees healthy. Although not implemented solely for pandemic planning, among the most notable elements is our very robust "telework" program, with a large number of our employees able to fully function from home. The second most significant capability includes comprehensive work re-allocation where customer service calls and claim adjudication can be redirected to other Aetna Offices with almost seamless transition. Another important element is that Aetna has a considerable bench of contingent workers who are trained and can augment critical staff if there are high absentee rates. Contingent workers are used to help handle peak customer service periods.

Another important line of defense is our capability to keep employees healthy in the face of a pandemic. Aetna has created many strategies to accomplish this. It starts with a short and pointed on-line course that all employees are expected to take. The course provides instructions for hand hygiene as well as sneeze and cough etiquette, because we believe, as others do, that this can be one of the best measures in minimizing the spread of a virus in the workplace. Aetna has placed hand hygiene and "stay home when sick" posters at all Aetna sites as constant reminders along with permanent intranet home page messaging. Aetna's HR policies strongly encourage sick persons to stay home when symptoms appear with non punitive pandemic pay policies.

Beyond these strategies, Aetna has provided a personal supply of antiseptic hand sanitizer to all office based persons within our facilities along with common space bulk hand sanitizer dispensers. Aetna has purchased a stockpile of surgical masks and has deployed supplies to site crisis managers with instructions to issue them to any person that is symptomatic or who may otherwise feel they may be coming down with the flu. Sick persons will be sent home or to a health care provider if symptoms are severe.

Another important planning element is our rapid telework deployment capability for office based workers. This is accomplished with infrastructure, procedures and plans where we can transition a very large number of workers to a temporary work at home setting within days using the internet. We implement a scaled down version of this each winter when severe winter weather occurs. During a traditional nor'easter, we typically have only 10-20 percent of employees coming to the office and our customers see little or no impact. Under Rapid Deployment, employees will be prioritized by mission critical function as well as by their technological readiness to transition. Efforts will be made to adhere to CDC guidance where employees in high health risk groups, be offered an opportunity to work at home however we are seeking clarity around the ADA provisions.

At many sites, there will still be a need for office-based workers to come on-site, no matter the threat, to keep serving our customers. For these employees, social distancing strategies will be employed. To that end, we have plans ready to cancel or curtail physical meetings and substitute virtual meetings through our robust teleconferencing capabilities. Additionally, we will enhance facility cleaning, controlling visitation, eliminate unnecessary travel, and spread out employees, if needed. Efforts will be made to coordinate actions with local health officials and adhere to any triggers that may be provided by health officials. All site crisis leaders have been instructed to establish two-way communications and contacts with their local public health officials so they are apprised of the local situation as it changes and are advised of local actions that should be taken.

The objective of all of this is to flatten the outbreak absentee curve at all affected sites and maximize our production to serve our customers and members during the peak of each wave. It is our hope that if all strategies are employed effectively, we can lessen the peak of that curve by at least 5-10 percent which will make a big difference.

A separate but very significant part of our response capability at Aetna is the ability to deal with member needs due to widespread disasters such as hurricanes, wild fires or terror attack. We have established a dedicated team to review health benefit policies that may need to change due to a provider network overload, failure or due to mass evacuation. Changes, once identified through our evaluation, or due to regulator order, will be communicated to members and plan sponsors so they can avail themselves of alternate ways to obtain the care they need. This process has been successfully demonstrated on 9 /11 and in natural disaster after disaster in recent years.

**Prepared Statement of Michael Kurland  
Director, Student Health Services  
University of Connecticut  
September 21, 2009**

**University of Connecticut Preparations for H1N1 Outbreak**

The University of Connecticut has a pandemic flu/continuity of operations committee which follows an operational plan based upon the NIMS model. This committee is comprised of representatives from a number of departments throughout the university, including Student Affairs, Student Health Services, Facilities, Academic Affairs, Public Safety, Environmental Health and Safety, Human Resources, the Office of the Attorney General, the Office of Communications, Finance, Regional Campuses and experts in emergency preparedness from Continuing Studies. The committee has been meeting for the past several months in order to plan for all aspects of health, safety and continuity of operations in the event of an H1N1 flu outbreak. The committee is chaired by Major Ron Blicher who serves as incident commander and in my capacity as Director of Student Health Services, I serve as the operations section chief.

Additionally, the Division of Student Affairs maintains an H1N1 Task Force which has been meeting weekly in order to operationalize plans for the health and safety of students and staff. This task force is comprised of representatives from Student Affairs, Student Health Services, Residential Life, Dining Services, The Office of Student Services and Advocacy, and Wellness and Prevention Services. Meetings have included staff from Environmental Health and Safety.

The issues addressed have included, but are not limited to the following:

- **Prevention strategies/Community education-** the university is embarking upon a multi-faceted health communications campaign in order to help prevent the transmission of the H1N1 virus. The focus is on respiratory etiquette, social distancing, proper hand washing, staying healthy, proper cleaning of personal and work space and encouraging students and staff to self isolate if they are infected with the flu. The methods of dissemination of information include bulletin boards, pamphlets, table tents, curriculum infusion, mass emails, letters, use of a dedicated H1N1 website, training of staff, cable TV and radio P.S.A.'s. The website includes many helpful links as well as FAQ pages for both employees and students. Additionally, students have been encouraged to be prepared and purchase supplies of hand sanitizer, fever reducing medications, fever thermometers and surgical face masks. Hand sanitizer has been made readily available in many public areas of the university and has been disseminated to students by many departments.
- **Isolation and support services-** the key to preventing transmission is to encourage isolation of sick people. Students who are ill are encouraged to call an Advice Nurse to seek medical assistance for the flu. They are provided with an assessment via the phone and are requested to visit the Student Health Service only if medically indicated in order to avoid burdening the healthcare system and reducing potential virus transmission. They are encouraged to remain isolated if they do not share a bedroom with another student. If they share a bedroom with another student, they are asked to return home if their family lives within driving distance.

Fortunately 85-90% of UCONN students live within driving distance of campus. If it is unfeasible to return home, the university has designated a number of beds to provide isolation for these individuals. Students who are self isolating or who have been moved to an isolation area are provided with meals delivered from Dining Services and are provided with a limited supply of "flu kits" and supplies such as Tylenol, Advil, fever thermometers and surgical face masks. If medically indicated, they will be admitted into the infirmary unit (inpatient) of the Student Health Service facility.

- **Academic considerations-** in order to reduce the transmission of H1N1, students are advised to be absent from classes if they have the flu. Professors have been advised to not require medical excuse notes and to expect higher than normal rates of absenteeism. Additionally, professors have been encouraged to utilize web based course tools which can assist students in keeping up with the curriculum in the event of illness.
- **Vaccination-** students are encouraged to receive both the seasonal flu vaccine as well as the H1N1 vaccine. Seasonal flu vaccine clinics have been scheduled earlier than usual. H1N1 vaccination clinics will be scheduled as soon as the vaccine is available. Doses of H1N1 vaccine have already been requested and will be provided free of charge to all students who fall within the target groups defined by the Centers for Disease Control (CDC).
- **Coordination with outside resources-** the university has been in close contact with the Connecticut Department of Public Health and has coordinated with the Eastern Highlands Health District, which is the health department for the local 10 town area.

**Current status:** As of this week the University of Connecticut has had 1 confirmed case of H1N1, 2 probable cases of H1N1 and less than 20 cases of influenza like illness (I.L.I.). We are monitoring the situation closely.

**Challenges:**

- Maintaining an ample number of isolation beds as the university residence halls are at 100% occupancy
- Maintaining "continuity of operations" in the event of large numbers of employee absences
- Maintaining an adequate amount of supplies to care for those sick with the flu
- Deciding when to cancel public events/classes due to large number of cases of the flu
- Staffing H1N1 vaccination clinics for an unprecedented number of inoculations
- Cost of supplies and personnel to accommodate the outbreak.

**H1N1 Flu: Monitoring the Nation's Response**  
**Homeland Security and Governmental Affairs Committee**  
Chairman Joe Lieberman  
October 21, 2009

Good morning. We have called today's hearing to discuss measures that have been taken so far to manage the spread of the H1N1 influenza virus, which reached pandemic proportions this summer and continues to claim new victims every day, especially among young people.

I want to thank Homeland Security Secretary Janet Napolitano, Health and Human Services Secretary Kathleen Sebelius, and Education Secretary Arne Duncan for being with us today. These are the three federal officials who have been coordinating the federal government and our nation's response to this public health challenge, which now can be called a public health crisis. We very much appreciate that you made the time to be with us here today for this oversight hearing.

Each of your agencies has critical responsibilities for dealing with the H1N1 public health emergency that has already taken the lives of thousands and thousands of people across the globe. Here in the U.S., the Centers for Disease Control and Prevention is no longer counting cases because the difficulty of staying on top of the increasing numbers and confirming those numbers. We do know that at least 2,300 people have died in the U.S. from H1N1 flu in the last few months.

Under existing federal government emergency protocols, the Department of Homeland Security is the overall incident manager, coordinating resources across the federal government and assisting state and local governments in their response to the H1N1 virus. The Department of Health and Human Services, including the CDC, has been responsible for leading the public health and medical response. And because this H1N1 outbreak poses greater risks for children than the traditional flu, the Department of Education has helped guide local districts on how to protect their students, under what circumstances to close schools, and what to do if a school must be closed.

This particular strain of influenza - H1N1 - has moved with alarming speed and taken an exceptionally high toll at a time of year when we don't normally encounter significant cases of flu. The CDC reports that the H1N1 flu has spread to all parts of the country, with almost all states reporting widespread or regional outbreaks. I want to draw your attention to the chart that my staff has prepared with information from the CDC and it gives you a sense of the course of the flu outbreak over the preceding three seasons. The H1N1 outbreak is now - at a time of year that's normally low in terms of flu impact - higher than the regular flu was at its peak in January. Of course this raises real concerns for us about where this line will go in the months ahead.

Alarmingly, young children are at very serious risk, with 43 pediatric deaths tallied so far this fall - 11 of which occurred just the week before last, the most recent period for which we have data. These pediatric mortality statistics for H1N1 flu are already equal to what we usually see over the entire course of a normal flu season for children. Presumably, and regrettably, these numbers will climb higher as the outbreak shows no signs of waning. Pregnant women are also

being hit hard by the flu. Of the over 100 pregnant women in intensive care through late August there were 28 deaths. The CDC, obviously, is quite concerned about that.

Thus far, the federal government in general, and the three of you and your agencies in particular, have responded aggressively and as effectively as possible to the threat of the H1N1 virus. You have quite skillfully tracked the spread of the disease and who it is afflicting. You have worked with private sector partners to develop a vaccine quickly. You have provided important information to guide state and local officials through perils they may face as the virus escalates. And you have remained very publically accessible and visible, communicating critical developments in this public health emergency to the American public. I presume that previous presidential directives and national strategies for infectious diseases and influenza pandemics that were issued over the last several years have informed and facilitated your decisions, which proves, once again, the immense value of planning. So there's a lot that should be reassuring and encouraging to the American people.

I want to say that I am concerned, as we meet this morning, that the flu is spreading so rapidly and in some cases with such intensity that it may well be getting ahead of the public health system's ability to prevent and respond effectively to it.

There are three aspects of the federal government's response to the H1N1 that are not reassuring, and I want to ask you directly about them and ask you to respond to them in your testimony. First, the schedule for vaccine production and availability - whose existence is really quite remarkable - that you set has slipped. The 28 million to 30 million doses that will apparently be available by the end of the month is 25 percent below initial governmental projections of the 40 million vaccines that you thought would be available by the end of October. There are now very unsettling reports of growing vaccine shortages that are leading a lot of people to ask if enough vaccine will be produced in time for all who will need it as we continue to experience the spread of H1N1 flu.

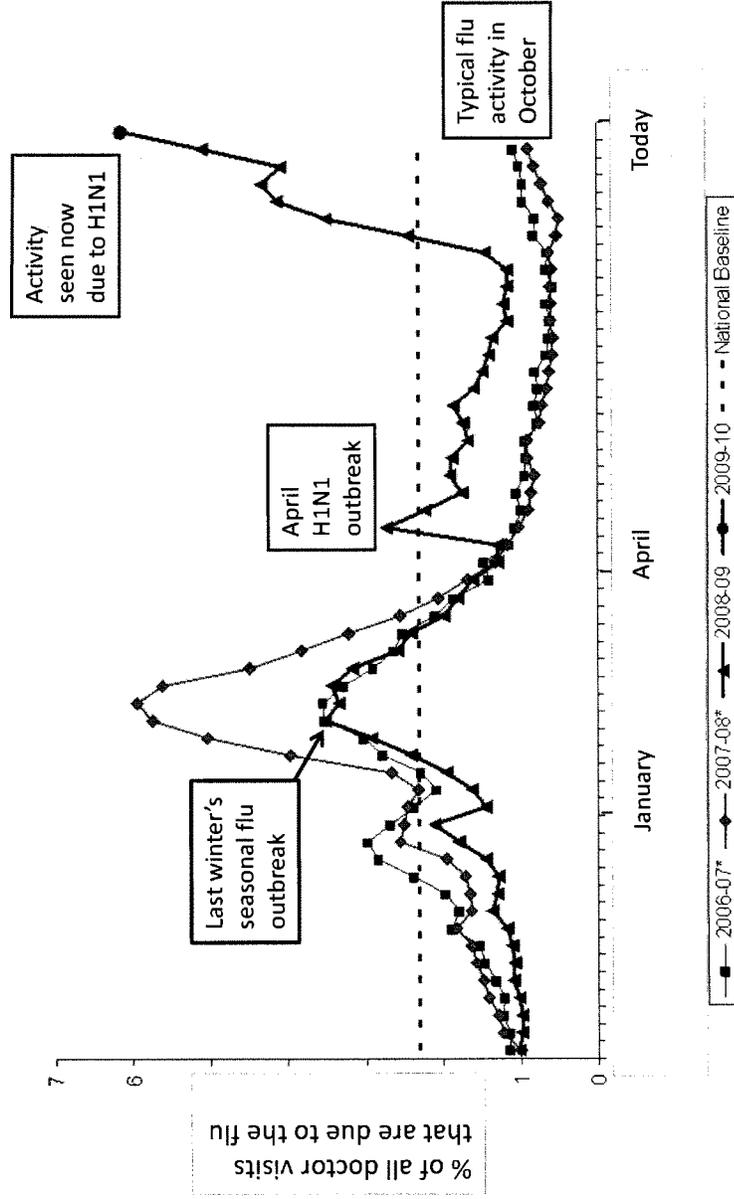
This week, one television reporter used the term "quiet desperation" to describe the feeling of public health officials around the country facing shortages of the H1N1 vaccine in their areas. That, I'm sure, is as unsettling and unacceptable a situation to you as it is to the rest of us.

Second, I want to express my concern that hospitals and public health departments do not have the capacity to care for the surge of people who may need hospitalization as a result of a spread of the virus. This is not a stunning new problem, we've worried about the capacity of our public health system, for instance, to deal with the consequences of a bioterrorist attack on the U.S.

I want to quote from a report this month from the Trust for America's Health that found that 27 states, including my own State of Connecticut, could exceed or come close to exceeding available hospital bed capacity during the peak of an outbreak, if 35 percent of the American people become infected with the flu, which the Trust says is a plausible number. Based on the 35 percent modeling scenario, more than a million people in Connecticut could develop the H1N1 virus, which would result in more than 17,300 hospitalizations at the peak of such an outbreak, which is about 150 percent of the total hospital bed capacity in Connecticut. I'm sure that situation repeats itself in other states and throughout the country.

My third concern is about the availability of intravenous anti-viral medications to treat the most critically ill with the H1N1 virus. Secretary Sebelius, you have an encouraging but general sentence in your written testimony about this. A recent report by the President's Council of Advisors on Science and Technology posed a plausible scenario in which 30 percent of the population would be infected with the H1N1 virus, resulting in almost two million hospitalizations. What particularly struck me was their estimate that between 150,000 and 300,000 of those hospitalizations could be so serious that they would require intensive care treatment. A lot of those people, from what I've heard from doctors, are probably not going to be able to be treated with the existing anti-virals, such as Tamiflu and Relenza. I know that HSS under the BARTA program, has actually been very farsighted about this and invested some money in some breakthrough work that's being done to develop intravenous retrovirals for those who are critically ill with this flu. This is one of those moments that poses a public health and ethical dilemma because they haven't fully completed all the trials. I want to hear about the state of development and of decision making about the availability of these intravenous anti-virals.

Bottom line, your departments have worked very aggressively and to the best of your ability. My concern is that this flu, the H1N1 virus, is moving very rapidly. While it seems to be affecting most people mildly, it is clearly affecting a small percentage quite seriously, so I am worried that the virus is getting ahead of the public health system's capacity at this moment to prevent it and respond to it. So it's with that sense that I thank you for being here and I very much look forward to your testimony.



\*There was no week 53 during the 2006-07 or 2007-08 influenza seasons, therefore the week 53 data point for those seasons is an average of weeks 52 and 1.

Source: Centers for Disease Control and Prevention, Fluview

Statement of  
Senator Susan M. Collins

**"H1N1 Flu: Monitoring the Nation's Response"**

Committee on Homeland Security and Governmental Affairs  
October 21, 2009

★ ★ ★

**By now, everyone in this room is familiar with the threat we currently face from the H1N1 influenza virus. This oversight hearing is important, however, because we must continue to assess the effectiveness of federal, state, and local efforts to respond to this pandemic, which appears to strike pregnant women, children, and young people with particular ferocity.**

**Just this past week in Maine, Bates College made the news when the number of H1N1 flu cases jumped from six to 160 within less than a week. As of yesterday, 245 Bates students are infected with H1N1.**

**Public health experts are learning as they go along, sometimes with surprising results that run counter to their earlier assumptions about H1N1. For example, the CDC just released a report that found that 46 percent of 1,400 adults hospitalized with H1N1 were healthy and did not have chronic illness before they got sick with the flu. While this was a preliminary analysis, the new report paints a different picture than previous studies, which concluded that the vast majority of H1N1 patients who became severely ill had chronic or other underlying health conditions. New data like this report must constantly be taken into account as we handle our nation's pandemic flu.**

**It is clear that much work has gone into preparing for this outbreak. Our country has mobilized as government officials at all levels, doctors and other health care professionals, non-profit organizations and private businesses have devoted significant time and resources to tackling the many challenges posed by this virus.**

**The Post Katrina Emergency Management Reform Act of 2006, written by this Committee, mandated comprehensive and coordinated disaster planning to improve our preparedness for both man-made and naturally occurring catastrophes like this pandemic. In addition, Congress has allocated nearly \$9 billion to HHS alone over the past five years for pandemic preparedness. These efforts laid the foundation for the strong response we have seen to date.**

**Page 2 of 2**

**Nonetheless, while the government and private sector have accomplished a great deal, significant concerns remain.**

**For example, despite the assurances of federal officials, millions of Americans are worried about the safety of the H1N1 vaccine. They want to know if it's safe to give to their children, what kind of testing was done, and whether it contains any dangerous additives. The state CDC in Maine reports many calls from citizens asking these questions.**

**State officials also remain concerned about whether there will be a sufficient number of doses of the vaccine. For example, in the next eight weeks, Maine is scheduled to receive only 340,000 doses of the vaccine. This falls short of the amount needed to vaccinate everyone in the priority groups that the CDC has identified.**

**I am disturbed by CDC's recent reports on the supply of vaccinations. CDC has been telling us since the summer that the federal government would have a sufficient supply of H1N1 vaccine to meet the demand; CDC also said that 40 million doses would be available by the end of October. It now appears production delays will result in 25 percent fewer doses than had been projected for this month.**

**Given that the virus disproportionately affects children, we also need to make sure that we have a sufficient supply of pediatric formulations of antiviral medications, like Tamiflu.**

**Another significant concern is whether or not our nation's emergency rooms have sufficient capacity to cope with a massive influx of sick patients if the pandemic worsens.**

**The fact that three Cabinet Secretaries are here today demonstrates the seriousness with which the federal government is preparing for and responding to the H1N1 pandemic.**

**I look forward to hearing from our witnesses. Thank you, Mr. Chairman.**

**###**

**Post-Hearing Statement for the Record  
Submitted by Senator Roland W. Burris**

**“H1N1 Flu: Monitoring the Nation’s Response”  
October 21, 2009**

Preparing for seasonal flu, which is unpredictable and troubling on its own, has become much more complex with the emergence of the H1N1 flu. In the months since it appeared, our nation’s emergency planners and health care personnel have emphasized the importance of prevention, mitigation, and control of H1N1 at the state and local levels.

The agencies represented here have made tremendous efforts to combat H1N1 thus far. This kind of interagency coordination, resource management, and workforce dedication will ultimately determine how H1N1 will affect us this flu season. From coordinating the federal response, to managing outbreaks in our schools and health facilities, I am confident that the guidance these agencies give to our communities will mitigate the impact of H1N1 flu on the nation.

I recently participated in a public service announcement detailing prevention and preparedness measures individuals can take to reduce the risk of contracting the H1N1 flu. It is my hope that through education we can teach people about prevention and minimize the influx of people checking into our hospitals and health facilities.

Although there have been exemplary efforts put forth so far, we are all aware of the problems a large scale H1N1 outbreak could pose to our critical infrastructure. Therefore, we must continue our efforts to educate the public, develop state and local preparedness plans, and optimize the use of our existing resources.

I would like to thank today’s witnesses for being here and look forward to your testimony.

**The Honorable Janet Napolitano**

**Secretary  
United States Department of Homeland Security**

**Testimony on  
“H1N1 Flu: Monitoring the Nation’s Response”**

**Before the  
United States Senate  
Committee on Homeland Security and Governmental Affairs**

**Dirksen 342  
October 21, 2009**

Chairman Lieberman, Senator Collins, and members of the Committee: Thank you for this opportunity to update you on all the steps we are taking to prepare Americans for the H1N1 flu epidemic.

In April, I testified before this Committee that DHS and our federal partners were addressing this situation aggressively – that was the case then, and it is still the case today. The federal response that began this spring has continued strong ever since.

In all of the actions we are taking to counter H1N1 flu, our thoughts are with those families and communities that have already experienced a loss due to this virus. Our sympathies go out to them today. Pursuant to President Obama's direction under Homeland Security Presidential Directive 5 (HSPD-5), the Department of Homeland Security has worked with a number of partners to support prevention efforts, coordinate business-of-government continuation planning, and assist the Department of Health and Human Services (HHS) in its efforts to distribute an H1N1 flu vaccine to the American population.

It is also important to note that some of the most important partners in the effort against H1N1 flu are our neighbors, our co-workers, and citizens across the country. Even as we continue to track the course of the H1N1 virus, the federal government has remained focused on keeping the public informed about this flu and what every person can and should do to help limit its spread.

As a result of what we learned in the spring about H1N1, the federal government has updated our response plans, enhanced our community mitigation planning and guidance, and improved a range of our abilities. These abilities include quickly pre-deploying antiviral medications to creating and disseminating messages that help the public understand what the Nation is facing. These improvements are not only critical to our H1N1 response, but are also critical to responding to future pandemics when they occur.

Close coordination among federal departments dealing with H1N1 flu has facilitated a strong response. Our partnerships with HHS, including the Centers for Disease Control and Prevention (CDC), with the Department of Education, and with other federal departments and agencies continue to play a critical role in our efforts. I am pleased to be here today with Secretary Sebelius and Secretary Duncan, who have provided critical leadership during this pandemic. Our other partners – from state officials to private sector leaders – have consistently noted that the level of collaboration across the federal government is unprecedented. Our goal has been to ensure that this collaboration exists not only among federal partners, but also among our private sector, government, and community partners throughout the country.

### *Planning*

The current outbreak of H1N1 flu manifested itself differently than the avian flu scenarios that the Nation had planned for. While much of that planning proved very useful in last spring's initial response, it generally contemplated a catastrophic, "worst-

case scenario” pandemic that originated overseas. As we continued to learn more about the H1N1 virus, we updated our plans to more accurately address the challenges and issues that are presented specifically by the H1N1 flu. At the same time, between the initial spring outbreak and the fall flu season, we prepared for a more severe H1N1 outbreak, should the virus mutate and cause more severe symptoms.

The Department of Homeland Security prepared a 2009-H1N1 Influenza Implementation Plan, which identifies specific component roles and responsibilities and ensures that all DHS components have developed plans that address a number of factors, including: key preparation and response actions; performance of mission-essential functions; workforce protection; continuity of operations; and communications with key stakeholders (including employees) during an H1N1 influenza outbreak.

Like the Department of Homeland Security, other federal partners used the last few months to strengthen the federal government’s response to a pandemic outbreak. All agencies and departments were asked to update their existing pandemic plans to ensure the continuation of mission-essential functions. On July 2, 2009, DHS and the White House reached out to federal agencies and departments, directing them to attend a pandemic flu training session led by FEMA’s National Continuity Programs Directorate (NCP), and to review their updated plans. Since July, NCP has held 30 interactive training sessions. DHS and the White House also asked federal agencies and departments to evaluate whether their plans met a series of standards established by FEMA. We received all evaluations by October 5, 2009.

With respect to operational support, DHS holds a central responsibility for providing timely and accurate data. To fulfill this mission, DHS deployed the H1N1 Common Operating Picture – a web-based tool on the Homeland Security Information Network (HSIN) – to collect information and provide data to our partners throughout the federal government and in the private sector, especially critical infrastructure and key resource (CIKR) sectors. This reporting tool exists not only to support DHS decision-making, but also to support the White House, our interagency partners, and state, local, private sector, and non-governmental partners. We anticipate the web-based Common Operating Picture will be a national hub for the exchange of critical information as we respond to the 2009 H1N1 outbreak in the months ahead.

*State, Territorial and Tribal Support*

Since the very first appearance of H1N1 flu, one of our priorities has been to work closely with state, local, tribal, and territorial governments. It is at these levels of government that officials administer public health programs, distribute vaccines to health care providers, and communicate with the public about how H1N1 is affecting individual communities. During the initial outbreak, we held daily conference calls with other federal agencies and with these partners – a step that was praised as essential and unprecedented. We continue to work to ensure that these levels of government have as much information as we do, when we do, and that we are supporting them and their efforts.

As part of this support, FEMA is providing specialized pandemic training for its National Response Coordination Center, 10 Regional Response Coordination Centers, and 56 Incident Management Assistance Teams–Advanced, known as IMAT-A. If required, these IMAT-A teams will deploy to states and territories at the request of the governor to participate in the states' unified coordinating groups alongside the governors' representatives. These teams would also assist in managing any requests for federal assistance. In addition, last month, FEMA activated a National IMAT dedicated to the 2009 H1N1 national response. This cell coordinates with DHS and HHS operations centers and is prepared to receive and evaluate requests for assistance from states and other federal agencies. Finally, FEMA is also coordinating with the Department of Defense to synchronize efforts between Defense Coordinating Officers and Federal Coordinating Officers if the H1N1 outbreak worsens.

In addition to FEMA, the DHS Office of Intergovernmental Programs (IGP) has resumed biweekly calls with all 56 state and territorial Homeland Security Advisors, in addition to tribal government representatives. These calls are critical to keeping partners updated on operational developments and soliciting feedback on pressing concerns. IGP also ensures that mayors, emergency managers, National Guard adjutant generals and other local and regional leaders receive updates on the H1N1 response. As I promised in April, I have continued to reach out personally to governors and mayors.

A key area of partnership with state, local, tribal, and territorial governments is the issuing of H1N1-related guidance for schools. DHS, the Department of Education, and HHS together released updated guidance for the K-12 education community on August 7, 2009. The guidance promotes routine ways to mitigate the spread of flu – such as frequent hand-washing and coughing into one’s sleeve – and encourages students and staff showing symptoms to stay home at least 24 hours after fever symptoms have ended. The guidelines also recommend that schools have plans in place to deal with people who are possibly infected. The guidance encourages schools to establish ways to continue educating children who are at home.

Through guidance and communication, we are ensuring that the federal government is working with state, local, and tribal governments on a unified response. We are also using this approach in relation to the private sector, which is an indispensable partner in combating H1N1 flu.

#### *Private Sector Outreach*

The private sector is particularly important in combating H1N1 – and not just the travel and hospitality industries, as was discussed during the initial spring outbreak. American businesses can help combat the flu by making workplaces as healthy as possible, and by having plans in place if a large number of employees have to stay home during a severe outbreak. This last consideration is especially important for private-sector partners who control critical infrastructure, such as hospitals or energy facilities.

DHS continues our engagement with businesses and critical infrastructure and key resources owners and operators. Starting with the initial outbreak in April, the DHS Private Sector Office provided regular phone briefings to private-sector partners on the latest developments. These briefings decreased in frequency as the situation reached a steady state; however, we are prepared to increase the use of these calls based on stakeholder requirements or scientific developments.

DHS teamed with HHS, including the CDC, to provide updated guidance to help the private sector best prepare for H1N1. DHS, the Department of Commerce, and HHS jointly released updated business guidance on August 19, 2009. DHS disseminated this guidance to our private-sector stakeholders. In conjunction with the business guidance, DHS also produced a small business guidebook on H1N1 preparedness. The small business guide, developed in consultation with interagency partners including HHS/CDC and the Small Business Administration, highlights how to make a plan to ensure continued operations, steps businesses can take to protect their environment, and steps employees can take to protect themselves from H1N1 flu.

Meanwhile, DHS is working to educate the owners and operators of critical infrastructure and key resources (CIKR) and small businesses on H1N1 preparedness. This work is occurring through national associations and organizations, the Sector-Specific Agencies and the CIKR Sector and Government Coordinating Councils, and the Department of Labor's Occupational Safety and Health Administration (OSHA). DHS is discussing

H1N1 preparedness and response on a weekly basis with Government Coordinating Council leadership, Sector and Government Coordinating Council joint calls, and the working groups associated with H1N1. This outreach has been considerable and continues to provide the most current developments and activities concerning H1N1.

*Workforce Protection*

The health and safety of the DHS workforce is one of my highest priorities. We must provide our personnel with the protections necessary to ensure that our mission-essential functions continue. We have benefited from the fact that DHS stockpiled personal protective equipment (PPE) and antivirals in advance of the H1N1 outbreak. PPE is pre-positioned at over 120 DHS locations and field offices nationwide, and the Department is prepared to deploy it as necessary.

Throughout the H1N1 response, we have provided DHS employees with new and updated guidance on a number of topics. These include guidance on seasonal influenza and H1N1 vaccines, antiviral medications, measures to reduce employee exposures, appropriate use of respirators for high and very high exposure risk occupations, full compliance with OSHA's respiratory protection standard, and human resources flexibilities – including leave and telework options – for employees as well as supervisors and managers. We have consistently worked to provide our employees with guidance based on the best science available. DHS is following HHS, CDC, and the Office of

Personnel Management's (OPM) publication, "Preparing for the Flu: A Communications Toolkit for the Federal Workforce" to help its employees prepare for flu season.

*International Coordination*

In addition to the extensive coordination with U.S. partners I have described, coordination with international allies is also critical – especially with those international allies with whom we share borders. We have worked throughout this outbreak to coordinate our response with Mexico and Canada. As the latest development in this partnership, on October 5, Deputy Secretary Jane Holl Lute traveled to Mexico City to join her counterparts from Canada and Mexico to discuss our continued international collaboration to confront the spread of the H1N1 virus.

Deputy Secretary Lute's meetings covered a wide range of H1N1-related issues. These included emergency information sharing and communication, border and customs-related issues, and the strategies each country is taking to respond to the spread of the H1N1 flu within its borders.

These types of international meetings are key to effective pandemic preparation. Our previous cooperation with Mexico and Canada led to the North American Plan for Avian and Pandemic Influenza – planning which proved very valuable during the response to the initial H1N1 outbreak in April 2009.

As I discussed in April, the efforts we have taken at our borders are based on risk and the best science available. Our officers and agents at U.S. borders and ports of entry continue to look for signs of illness in people who are crossing, and we will continue to guide our measures at our borders with what the best science tells us to do.

*Conclusion*

When I testified before this Committee in April on the steps we were taking to address H1N1 flu, I described a number of actions to respond to an initial outbreak. Our efforts have not wavered since – the federal response has continued to be strong, coordinated, and based on science, though we have altered some approaches as we have learned more about the H1N1 flu virus and how we can best keep Americans safe from it. Throughout the response to H1N1 flu, we have engaged closely with federal interagency partners such as HHS/CDC, and the Department of Education, in addition to the White House. We also have worked closely with state, local, tribal, and territorial governments and with the private sector to mitigate and monitor the spread of this disease. While we do not know the ultimate course of H1N1 flu, Americans can be confident that this Administration is working on all fronts to combat it.

Chairman Lieberman, Senator Collins, and members of the Committee: Thank you again for this opportunity to testify on the actions we are taking to mitigate the effects of H1N1 flu. I will be glad to answer any questions you may have.

	<p><b>Testimony before the Committee on Homeland Security and Governmental Affairs United States Senate</b></p>
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**2009 H1N1 Influenza:  
Monitoring the Nation's Response**

*Kathleen Sebelius*  
*Secretary*  
*U.S. Department of Health and Human Services*

**For Release upon Delivery  
Expected at 9:30 a.m.  
October 21, 2009**

Chairman Lieberman, Ranking Member Collins, members of the Committee, thank you for this opportunity to update you on the Nation's response to the 2009 H1N1 influenza. I want to assure the Committee that the Administration is taking the public health challenges seriously, and is implementing a comprehensive strategy to monitor and address H1N1 throughout this fall and winter. HHS continues to work in close partnership with virtually every part of the federal government under a national preparedness and response framework for action that builds on the efforts and lessons learned from this spring. Working together with governors, mayors, tribal leaders, state and local health departments, the medical community and our private sector partners, the federal government has been actively implementing a vaccination program and revising and refining plans and activities based on new data and information.

#### **Tracking and Monitoring Influenza Activity**

Since the initial spring outbreak of 2009 H1N1 influenza, this virus has triggered a worldwide pandemic, and was the dominant flu strain in the southern hemisphere during its winter flu season. Data about the virus from around the world have shown that the circulating pandemic H1N1 virus has not changed significantly since the spring. The virus remains similar to the virus chosen for the 2009 H1N1 vaccine, and remains susceptible to the antiviral drugs oseltamivir and zanamivir, with rare exception. As with seasonal influenza, persons with some chronic health disorders and pregnant women have a higher risk of severe disease. In contrast to seasonal influenza, elderly persons have proven less likely to contract the virus; nevertheless, many elderly persons who do contract the virus have had serious complications, so early treatment with antivirals is recommended for them, as it is for pregnant women and others at high risk for complications, and for anyone who becomes seriously ill.

Unlike our typical seasonal flu, we continued to see flu activity in the United States over the summer, notably among school-aged children and young adults. More recently, we have seen widespread influenza activity in most states. Visits to doctors for influenza-like illness are much higher than levels expected for this time of the year. We are already observing that more communities are affected than those that experienced outbreaks this past spring and summer, reflecting wider transmission and potentially causing greater impact. For example, 86 pediatric deaths related to 2009 H1N1 flu have been reported to the Centers for Disease Control and Prevention (CDC) since April 2009, a level that has only been seen at the peak of past influenza seasons. During the week of October 4 - 10, 2009, 11 deaths were reported. In each of the past three years, between 46 and 88 children died from seasonal influenza. Over the next several months, seasonal influenza viruses may circulate along with the 2009 H1N1 influenza virus, and it will not be possible to determine quickly if ill individuals have 2009 H1N1 influenza, seasonal influenza, or other respiratory conditions based on symptoms alone. Because of this, close monitoring of viruses in the United States will be critical to ensure that the best guidance about treatment and prevention of influenza can be provided.

#### **Enhancements Made to the Tracking of Influenza Illness and Death**

Because of the current pandemic, several additional systems have been put in place or modified to more closely monitor data on the impacts of 2009 H1N1 influenza. These changes include the following:

- *Enhancing Hospitalization Surveillance:* CDC has greatly increased the capacity to collect detailed information on patients hospitalized with influenza. Using the 198

hospitals in the Emerging Infections Program (EIP) network, CDC monitors a population of 25.6 million to estimate hospitalization rates by age group and monitor the clinical course among persons with severe disease requiring hospitalization. The EIP sites also track vaccine effectiveness.

- *Expanding Testing Capability:* Within two-and-a-half weeks of first detecting the novel 2009 H1N1 virus, CDC had fully characterized the new virus, disseminated the information to researchers and public health officials, and developed and begun shipping to states a new test to detect cases of 2009 H1N1 infection. CDC continues to support all states and territories with test reagents, equipment, and funds to maintain laboratory staff and ship specimens for testing. In addition, CDC serves as the primary support for public health laboratories around the globe and has provided test reagents to 295 laboratories in 147 countries. It is vital that accurate testing continue in the United States and abroad to monitor any changes in the virus that may indicate increases in severe infection, resistance to antiviral drugs, or a decrease in the match to circulating vaccine strains.
- *Monitoring severe illness and mortality of women who are pregnant:* Pregnant women are a group known to be at a higher risk for seasonal influenza. Similarly, data indicate that pregnant women also are at higher risk of severe disease and death from the 2009 H1N1 influenza virus. CDC is in the process of implementing a new system to collect data on severe illness (intensive care hospitalization) and mortality among pregnant women, which will improve our ability to monitor this group.

- *Aggregate Hospitalizations and Deaths Reporting Activity (AHDRA)*: To supplement several well-established influenza surveillance systems, CDC introduced an interim data collection activity to augment information on hospitalizations and deaths in 2009. This supplemental activity collects information from all 50 states to identify hospitalizations and deaths due to influenza or influenza-like-illness (ILI) nationally and within each state. Jurisdictions now can report to CDC either laboratory-confirmed or clinical pneumonia counts of hospitalizations and deaths. Initiated on September 1, 2009, this new collection activity will contribute to a more complete picture of the burden of serious influenza and pneumonia illness and deaths during the pandemic and let each state examine trends in the course of the pandemic in their areas.
- *Health Care System Readiness*: HHS is also using multiple systems to track the impact of the H1N1 outbreak on our healthcare system. HHS and CDC are in constant communication with state health officers and hospital administrators to monitor stress on the healthcare system and to be prepared in case federal medical assets will be necessary to augment state and local surge capabilities. To date, state and local officials have been able to accommodate the increased patient loads, but this is something we need to monitor very closely, and we need to be prepared to respond quickly if the situation warrants.

#### **Shared Responsibility and Science-Based Guidance**

Slowing the spread and reducing the impact of 2009 H1N1 and seasonal influenza is a shared responsibility, and we all need to plan for what would need to be done when the flu impacts our

community, school, business, or home this fall. Given that the virus already is circulating in the United States, it is important for every American family and business to prepare their own household and business plans and think through the steps that will have to be taken if a family member or co-worker contracts the flu.

HHS has provided specific recommendations for what individuals, including people with certain health conditions at high risk of complications, parents, pregnant women, caregivers, and seniors, can do to prevent respiratory infections. We emphasize frequent hand-washing as an effective way to reduce transmission of infections. It is very important for sick individuals to stay at home, and for parents to keep children who have a fever or flu-like illness home from school, childcare, the playground, or other places children gather. Similarly, sick individuals should not get on an airplane or any public transport. Taking personal responsibility for these activities will help reduce the spread of this new virus as well as other respiratory illnesses.

HHS values the collaborative relationships established with our partners at the Departments of Homeland Security and Education and has leveraged these relationships to develop clear and actionable guidance for schools and businesses. In close collaboration with the Department of Education, CDC has released guidance and information for K-12 schools, as well as universities and colleges, advising administrators on the measures that can be taken to mitigate disease spread in educational settings while limiting the disruption of day-to-day activities and the vital learning that goes on in schools and institutions of higher education.

CDC, in close collaboration with the Department of Homeland Security (DHS), has updated its recommendations to assist businesses and other employers of all sizes. On August 19 DHS, CDC, and the Department of Commerce jointly announced guidance for businesses entitled, "*CDC Guidance for Businesses and Employers to Plan and Respond to the 2009–2010 Influenza Season*," which is available on the flu.gov website. In early September, CDC, DHS, and the Small Business Administration released additional guidance specifically developed to help small businesses prepare for how this new virus may impact them.

CDC has also collaborated with the U.S. Office of Personnel Management (OPM) in updating its recommendations to federal departments, agencies, and employees. On October 1, HHS and OPM released guidance to help federal agencies and employees implement recommendations from CDC in planning and responding to the 2009-2010 influenza season, entitled "Preparing for the Flu; a Communications Toolkit for the Federal Workforce," which is available on the flu.gov website.

HHS and the Department of Labor issued new guidance to address infection control and worker safety in healthcare settings. The updated infection control guidance was finalized on October 14. These comprehensive guidelines provide advice on how healthcare institutions can guard against the flu and mitigate its spread. CDC also has issued guidance for healthcare providers about the appropriate use of antiviral drugs to treat patients who are at highest risk from complications from the seasonal and 2009 H1N1 influenza.

Our recommendations and action plans are based on the best scientific information available to help our nation respond aggressively and effectively to the 2009 H1N1 virus. We are working to

ensure that Americans are informed and consistently updated with information in clear language. This is a dynamic situation, but it is essential that the American people are fully engaged so they can be part of the response. The federal government, particularly CDC, will be conducting weekly and, when necessary, more frequent briefings that will be available at flu.gov to get critical information out to the American people.

#### **Vaccination Program**

With unprecedented speed, we have completed key steps in the vaccine development process – we have characterized the virus, identified a candidate strain, expedited manufacturing, and performed clinical trials and licensed four 2009 H1N1 influenza vaccines. The speed of this vaccine development was made possible due to the investments made through the Office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) over the past six years in advanced research and development and infrastructure building. The rapid responses of HHS agencies, including CDC, NIH, and FDA in terms of surveillance, viral characterization, pre-clinical and clinical testing, and assay development, were greatly aided by preparedness efforts for influenza pandemics set in motion by the H5N1 outbreak in 2003.

After close collaboration with state and local authorities and the clinical community, we began the voluntary 2009 H1N1 national vaccination program at the beginning of this month. Critical support from Congress resulted in \$1.44 billion for states and hospitals to support planning, preparation, and implementation efforts. States and cities began placing orders for the 2009 H1N1 vaccine on Wednesday, September 30. The first vaccination with 2009 H1N1 influenza vaccine was given Monday, October 5. Vaccine shipments will continue each week into

December and, if necessary, January. Vaccine will become increasingly available in a variety of settings, such as vaccination clinics organized by local health departments, healthcare provider offices, schools, pharmacies, and workplaces. CDC continues to offer technical assistance to, and meets regularly with, states and other partners to improve the effectiveness of the vaccination program.

The vaccine is available free-of-charge to the American people, but some public and private providers may charge a fee or bill insurance companies to cover the cost of administering the vaccine. The vaccine is being distributed to providers and state health departments similarly to the way federally purchased vaccines are distributed in the Vaccines for Children program. Two types of vaccine are now available: vaccine that is injected and is made from inactivated virus, and vaccine that is given nasally and is made from live, attenuated (weakened) virus. CDC continues to work with a contractor and the states to deliver vaccine to sites across the United States.

CDC's Advisory Committee on Immunization Practices (ACIP) has recommended that the 2009 H1N1 vaccines be directed to target populations at greatest risk of illness and severe disease caused by the 2009 H1N1 virus. Mindful of these risks and the need to ensure protection of those responsible for caring for Americans when they are sick, the ACIP recommended on July 29 to target initial doses of the new H1N1 vaccine to five high-risk groups comprised of approximately 159 million people. CDC accepted these recommendations. These groups are: pregnant women; people who live with or care for children younger than 6 months of age; health care and emergency services personnel; persons between the ages of 6 months through 24 years of age; and people from ages 25 through 64 years who are at higher risk for severe disease due to

2009 H1N1 because of chronic health disorders like asthma and diabetes or compromised immune systems. Within that target group, the ACIP noted that during times of very limited vaccine availability, the highest-risk subgroups within the target groups should be identified to receive the earliest doses of vaccine. Those subgroups include: pregnant women; people who live with or care for children younger than 6 months old; health care and emergency services personnel with direct patient contact; persons between the ages of 6 months and 4 years; and persons from ages 5 through 18 with chronic health disorders or compromised immune systems.

Since September 30, when the 2009 H1N1 vaccine was first made available to states to distribute, the number of doses that has been produced, distributed, and administered has grown steadily, and states are executing their plans for providing vaccine to high-priority populations. While modest amounts of vaccine have been made available ahead of schedule, a series of manufacturing delays has caused significant reductions in the manufacturers' projected vaccine output. These delays are affecting both the U.S. and global vaccine supplies. Although we had hoped to have more vaccine distributed by this point, ultimately everyone who wants to get vaccinated will be able to, and we are working hard to get vaccine out to the public just as soon as we receive it.

Our experience with the ups and down of the vaccine manufacturing process has made clear the need to enhance our country's vaccine manufacturing capability. Not only are we dependent on companies based in other countries, we are using decades-old technology that must be improved upon. HHS is committed to developing cell-based and other technologies to increase our vaccine manufacturing capacity. In fact, we need to make all aspects of the manufacturing process appropriate for the 21<sup>st</sup> century. This will not just help the United States; it will help the world.

It is important that when the next pandemic hits, we are better prepared to mount a speedy, agile response.

#### **Vaccine Safety**

Vaccine safety has been and continues to be a top priority for us with the 2009 H1N1 vaccine. Because the 2009 H1N1 influenza vaccine is made in the same way as seasonal influenza vaccines, we expect it to have a similar safety profile as seasonal flu vaccines, which have a very good safety track record. CDC and the Food and Drug Administration (FDA) work in cooperation with state and local health departments, healthcare providers, and other partners to closely monitor the safety of seasonal influenza and other vaccines licensed for use in the United States. CDC, FDA, and other partners will use several systems to monitor the safety of 2009 H1N1 monovalent influenza vaccine. Two primary systems that will be used are the Vaccine Adverse Event Reporting System (VAERS), which is jointly operated by the CDC and FDA, and the Vaccine Safety Datalink (VSD) project, which is managed by CDC. These systems have been strengthened, and new systems have been developed to provide more monitoring of the safety of H1N1 vaccination.

Although we expect to have enough vaccine available for all who wish to be vaccinated by the end of this year, we need to remind all Americans about the things they should continue to do to curtail the spread of this virus: washing hands, staying home if you are sick, and taking the necessary precautions to stay healthy and avoid getting sick.

While we all are very focused on the 2009 H1N1 influenza virus, it is important that we do not forget the risks posed by seasonal flu viruses, which typically peak during the winter months.

More than 36,000 people die each year from complications associated with the flu. However, we do not know the extent of disease that seasonal viruses will cause this winter or spring. CDC continues to recommend vaccination against seasonal influenza viruses, especially for all infants, children, and people at greater risk for influenza complications. As of October 9, 82 million doses of seasonal vaccine have been distributed. While some parts of the country are experiencing shortages, more doses are expected in November.

#### **Clinical Trials**

Clinical trials on 2009 H1N1 influenza vaccine began in July and are ongoing. Early information from these trials suggests that the safety profile of the vaccines trigger similar immune responses to seasonal vaccine. The clinical trials will determine, and if necessary further guide, the optimal use of these vaccines based on the levels of antibodies produced. One dose of vaccine induces what is likely to be a protective immune response in most healthy adults and children 10-17 years old. Children younger than 10 years should receive two doses of 2009 H1N1 flu vaccine. The trials are also seeking information on pregnant women and on immune-compromised individuals.

#### **Antiviral Distribution**

In the spring, anticipating commercial market constraints, HHS deployed 11 million courses of antiviral drugs from the Strategic National Stockpile (SNS) to ensure the nation was positioned to quickly employ these drugs to combat H1N1 and its spread. This action has been effective in allowing the nation to deal with spot shortages of antiviral drugs and limitations on supplies of products targeted for young children, including liquid preparations authorized for emergency use in infants less than 1 year of age. Earlier this month, HHS made available to states an additional

300,000 regimens of the antiviral pediatric oral suspension to mitigate a predicted near-term national shortage indicated by commercial supply data. Physicians treating critically ill patients with H1N1 influenza will soon have access to new antiviral drugs supported by HHS/BARDA and administered intravenously under a CDC-sponsored Emergency Use Authorization.

#### **Major Communication Efforts**

HHS continues to develop and strengthen major communication efforts as part of the public health response. This includes broad distribution of public service announcements, news reports, and other traditional media; use of social media such as podcasts, blogs, and Twitter; and frequent phone conferences with numerous physicians and other partner groups. The Department and its agencies also are collaborating with the White House on public engagement efforts to reach organizations that serve populations who are most vulnerable.

#### **Closing Remarks**

At HHS, we are working hard to understand and help control this pandemic and to keep the American people informed. We are working in close collaboration with our federal partners, health departments, and health-related organizations to make improvements and continue to build upon our current response. Our ability to respond is a direct result of the investments and support of Congress, and the hard work of state, local, tribal, and territorial public health officials and our partners in the private and not-for-profit sectors. Building strong systems to track and monitor seasonal influenza has allowed us to closely monitor the impact of this novel virus on our communities. While we must remain vigilant, at no time in our nation's history have we been more prepared to face this kind of challenge.

We look forward to working closely with Congress to best address the situation as it evolves in the weeks and months ahead. Again, Mr. Chairman, thank you for the opportunity to participate in this hearing with you and your colleagues. I look forward to your questions.

**Testimony of Secretary Arne Duncan  
U.S. Department of Education  
U.S. Senate Committee on Homeland Security and Governmental Affairs  
“H1N1 Flu: Monitoring the Nation’s Response”  
October 21, 2009**

*For Release Upon Presentation (October 21, 2009; 9:30 a.m.)*

**Thank you Chairman Lieberman, Ranking Member Collins and Members of the Committee for inviting me to testify before you, today. And thank you Secretary Sebelius, and Secretary Napolitano – the interagency coordination and cooperation in the Federal H1N1 effort—from top to bottom—has been extraordinary. I also want to thank Dr. Thomas R. Frieden, the Director of the Centers for Disease Control and Prevention (CDC).**

**Our team at the Department of Education has been working very closely with the Departments of Health and Human Services (HHS) and Homeland Security (DHS) and the CDC since the initial outbreak of the H1N1 influenza in April, to prepare thoughtful guidance for early learning programs, elementary and secondary schools, and institutions of higher education. It has been an incredible team effort, one that can serve as a model for dealing with other problems and issues that cross agency boundaries.**

**I want to spend most of my time this morning discussing our efforts to keep children, students, faculty, and staff safe during the fall wave of the H1N1 pandemic.**

**While I want to concentrate on our current efforts, and by ‘our’ I mean all our agencies, I think it is important to also look back to see where we were in the spring. I think you will agree that we have made significant progress in a very short period of time.**

**Spring**

**In the spring, from April to June, we found that schools closely followed school-dismissal guidance developed by the CDC. For example, on April 26, 2009, the CDC advised schools to consider closing when they had a confirmed or suspected case of H1N1 – and we found that schools adhered to that advice.**

**On May 4, the CDC revised the guidance to state that schools should not close “unless there is a magnitude of faculty or staff absenteeism that interferes with the school’s ability to function” – and fewer schools closed and many that were closed reopened. From April 27 through June 12, more than 1,350 schools in 35 states and the District of Columbia closed for at least one day. Those closures affected 824,966 students and 53,217 teachers. The greatest number of school dismissals occurred on May 5, when 980 schools and 607,778 students were affected.**

**As school districts started to implement the new guidance on closures, those numbers rapidly declined.**

**The lesson we learned in the spring was not only that schools follow the CDC’s advice on flu-related issues, but also that quickly closing a school is a complex undertaking that has consequences beyond the loss of valuable school time. For example, unplanned school closures led to the loss of school meals for some of the 31 million kids who rely on the federal school meals programs; loss of wages for parents who had to stay home from work to take care of their children; and older students left home without proper supervision.**

**Further, we learned that we had to develop a new way to track school closures and dismissals; the way we were doing it didn’t work well, especially when there were a large number of schools that were closed.**

### **Fall**

**Examination of our efforts during the spring outbreak helped us to understand where we could do better. In particular, we needed to do several things:**

- **First, we needed to offer schools balanced, measured, clear, and concise guidance that reflects the best science available.**
- **Second, we needed to design a tracking system that provides accurate and timely data on school dismissals.**
- **Third, we needed not only to continue to reach out to those we reached in the spring, but to a much expanded audience. Getting the message out and making sure it is the right message, and getting it out quickly**

**and to as many schools, school officials, and parents as possible is the key to our communication strategy.**

- **Fourth, and finally, we needed to develop more materials for schools and educators and to develop those materials in a format that made them understandable and useful to schools and educators.**

**Let me briefly expand on each of these points.**

**With regard to the first point on guidance, we knew that while in a limited number of cases school dismissals were warranted, if conditions in the fall mirrored those in the spring, schools could remain open as long as they took various prudent measures, such as encouraging educators and students to practice good hygiene such as washing hands and coughing into the elbow, having students stay home if they are sick, and practicing social distancing such as rearranging desks so students are further apart.**

**With regard to the second point, we developed a new K-12 school dismissal tracking system this summer.**

**The new school dismissal monitoring system is a collaborative effort between the CDC and the Department and is supported by state and local health and education agencies, as well as national nongovernmental organizations; the system is built on a nationwide Federal and State partnership. The new voluntary system includes daily, direct reporting from state and local agencies as well as daily, systematic searches and confirmations of media reports.**

**As noted, from April 27 through June 12, our data suggest that more than 1,350 schools with 823,966 students and 53,217 teachers closed for at least one day.**

**However, from August 3 through October 9, we had 501 schools from 31 states closed for at least one day. These closures affected 186,074 students, and 12,063 teachers. Thus far this school year, our data suggest that the greatest number of school dismissals occurred on October 9, when 129 schools and 36,926 students were affected. We estimate that this represents less than one percent of the number of schools and one percent of the number of students.**

**As a front page story in the NY Times on October 8, 2009 pointed out, “[a]ttendance in the New York City’s public school system, with just over a million students, was 91 percent Wednesday. Last spring, when the virus was rampant, nearly 60 schools were closed and about 18 percent of students were absent.”**

**The reductions in the number of schools that closed as a result of H1N1 are a direct result of a number of things, ranging from a flu with moderate severity to improved messaging and outreach.**

**In our effort to prepare the education community for H1N1, and to prevent the virus from spreading to a point that it disrupts education, there is a role for nearly every major stakeholder group to play.**

**Over the summer, I convened a group of representatives from education’s major associations—those representing teachers, principals, school administrators, school boards, colleges and universities, counselors, and, very important, school nurses and parents. We talked about ways that each sector could contribute to this massive preparation and prevention effort, and I want to commend these groups for answering the call.**

**For instance, the National Association of School Nurses, the National PTA and the National Association of School Psychologists collaborated on a guide for parents, to help them talk to their children about H1N1 and support prevention methods. Available initially in English and Spanish, that guide—and so many other useful H1N1 resources—has been translated into other languages, as well. The school nurses association recently heard of interest in using it in Japan.**

**Also, in September, HHS, CDC, and ED held a call for child care providers to discuss the steps to be taken by providers and parents of young children to keep everyone safe.**

**The Department of Education has also been working with the business community, especially educational publishers and national companies in media and technology, to make resources available so that students can continue learning if they are home sick or their school is dismissed. Thanks to these companies’ commitments, America’s students will have a variety of hi-tech and low-tech ways to stay connected to their classrooms.**

**While our prevention efforts must and will continue, we are now putting the full-court press on the importance of vaccinating children.**

**We realize that vaccinating students is the best way to ensure that the flu does not spread among students. We have made available for all 14,000 plus school districts an easy-to-read document that explains how schools can work with public health officials to establish or host a vaccination clinic. Also, CDC has provided a sample letter for schools to use to get parental consent for the vaccine now so shots can be given as soon as they become available.**

**I'm delighted to say that we have seen some terrific examples of various states doing this well.**

**For example, the Rhode Island Department of Health has made plans to operate clinics in all schools in the state, using licensed medical professionals enrolled through its Statewide Emergency Registry of Volunteers. The Health Department plans to vaccinate middle and high school students during the school day and offer after-school and weekend clinics for elementary students.**

**In Kansas, the Sedgewick County Health Department has partnered with several local public and nonpublic K-12 schools in the Wichita area, as well as higher education institutions, to provide vaccines through school clinics.**

**And in Utah, the Salt Lake Valley Health Department has solicited bids from nursing agencies to provide vaccinations in schools. These providers already have demonstrated capacity for managing large efforts. Timing may vary by school but officials envision setting up clinics in large spaces, such as an auditorium, and vaccinating one class at a time those students whose parents have provided consent.**

**All of these efforts have led to schools that are as prepared as they can be to handle the flu. Again, thank you for allowing me to testify today. I am happy to answer any questions you may have.**

<b>Question#:</b>	1
<b>Topic:</b>	workforce
<b>Hearing:</b>	H1N1 Flu: Monitoring the Nation's Response
<b>Primary:</b>	The Honorable Daniel K. Akaka
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Questions and Answers for the Record  
Submitted by Janet Napolitano, Secretary,  
U.S. Department of Homeland Security**

**Question:** I have long been concerned with the potential effects of an influenza pandemic on the federal workforce and government operations. Could you describe how the Department is tracking the spread of H1N1 flu within its workforce, what resources or services are being provided to infected workers, and what information is provided to other employees who may have been exposed to H1N1?

**Response:** DHS set up an internal workgroup with the Office of the General Counsel (OGC), Privacy, the Office of Health Affairs (OHA), Office of Operations and Coordination (OPS), and the Office of the Chief Human Capital Officer (OCHCO) to review options available to track H1N1 in our workforce. Due to privacy and operational concerns surrounding any request to an employee that they divulge the nature of their illness, it was determined that the Department would instead track both annual and sick leave data in the aggregate and compare it to annual and sick leave data from last year. The Department will also track daily readiness. Absenteeism data will be reviewed by our scientists to estimate the impact of pandemic influenza on DHS workforce absenteeism.

All currently infected workers have been referred to their local healthcare provider or USCG medical staff for treatment. In the event that healthcare resources became scarce, DHS has procured antivirals for our workforce and developed policies and procedures to allow us to dispense them to workers who have identified themselves as ill and meet CDC guidelines.

DHS has posted guidance that is accessible through the Department's intranet and internet sites. The internet site is accessible at [http://www.dhs.gov/files/programs/gc\\_1241202408781.shtm](http://www.dhs.gov/files/programs/gc_1241202408781.shtm). Guidance includes information on protective measures and human resources strategies to prevent the spread of influenza, as well as messages from Department leadership. In addition, OCHCO has produced training materials for the workforce and management, which include resource documents, frequently asked questions, and a revised video on pandemic influenza. The workforce guides produced by OCHCO, and revised video message from the DHS Chief Medical Officer, reinforce the mission-specific H1N1-related training offered by DHS Components.

<b>Question#:</b>	2
<b>Topic:</b>	stockpile
<b>Hearing:</b>	H1N1 Flu: Monitoring the Nation's Response
<b>Primary:</b>	The Honorable Daniel K. Akaka
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:** In FY 2006, the Department started to purchase personal protective equipment (PPE) for use by mission-essential employees and to stockpile antiviral medications to protect its workforce. Please provide information about the Department's current PPE and antiviral stockpiles. Does the Department anticipate that these stockpiles will be sufficient to protect its employees? If not, what steps are being or should be taken to ensure that DHS has an adequate supply of PPE and antivirals for its workforce?

**Response:** DHS Office of Health Affairs has stockpiled the following personal protective equipment (PPE):

- Over 7 million N95 respirators
- 7 million surgical masks
- 10 million pairs of gloves
- 600,000 disposable garments
- 48,000 goggles
- 450,000 bottles of hand sanitizer

This PPE is pre-positioned at over 120 field locations throughout the DHS Components for the purpose of protecting the DHS workforce during pandemic outbreaks. FEMA has secured a DPAS rating for the purchase of respiratory protection that has been agreed to by HHS. In addition, operational components such as TSA and CBP have purchased masks for their workforce.

The PPE stockpiles are sufficient to protect mission employees for an estimated duration of 15 to 30 days (depending on usage demand and pandemic severity). DHS is monitoring the stockpile quantities at the Components, and only the hand sanitizer quantities have been substantially drawn down due to the 2009 H1N1 outbreak.

DHS is in the process of establishing BPA (blanket purchase agreement) contract vehicles with the distributors of PPE products (estimated award date late calendar year 2009). These contracts will be available to all DHS Components to purchase against, with pre-negotiated pricing and terms.

Furthermore, DHS stockpiled antiviral medicine for the DHS workforce, which is located in secure pharmaceutical warehouse locations positioned for rapid distribution. The DHS antiviral stockpile is sufficient to cover all DHS employees with at least one treatment course per employee. Under current CDC guidance, this is sufficient to protect DHS employees.

DHS has established IDIQ (indefinite delivery indefinite quantity) contract vehicles with the antiviral manufacturers with pre-negotiated pricing and terms to ensure DHS can quickly purchase additional quantities of antivirals in the future if current stockpiles are rapidly depleted.

<b>Question#:</b>	3
<b>Topic:</b>	PPE
<b>Hearing:</b>	H1N1 Flu: Monitoring the Nation's Response
<b>Primary:</b>	The Honorable Daniel K. Akaka
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:** As Chairman of the Federal Workforce Subcommittee, I held a hearing in June entitled, "Protecting Our Employees: Pandemic Influenza Preparedness and the Federal Workforce." At the hearing, I expressed my concern that employees who interacted with travelers daily at the Customs and Border Protection and Transportation Security Administration were receiving conflicting guidance about how to protect themselves from the H1N1 flu. At the hearing, Under Secretary Duke stated that Transportation Security Officers (TSOs) were permitted to wear PPEs. I appreciate the Department's efforts to update its workforce policy on using PPE. However, I recently have heard concerns that TSOs are not being given clear guidance on how they can access PPEs.

If employees whose work requires them to come in close contact (less than six feet) with members of the public volunteer to wear PPE, how does the Department ensure that they are able to easily access PPEs?

**Response:** The Department of Homeland Security (DHS) purchased over 7 million respirators and 7 million surgical masks to ensure our front-line employees are fully protected. The respirators and masks were shipped throughout the U.S. to border patrol stations, airports, detention centers, and other locations where our employees work and where the items can be made readily available to them.

On August 17, 2009, the Department's Under Secretary for Management Elaine Duke issued a memo announcing H1N1 guidance for employees (Attached). Voluntary use of respiratory protection was included in the guidance for low and medium exposure risk work activities, as described in OSHA Document 3327-02N, *Guidance on Preparing Workplaces for an Influenza Pandemic*. Respiratory protection is mandatory for higher risk groups within DHS. This information is available to all DHS employees and is posted on the public DHS website at [http://www.dhs.gov/files/programs/gc\\_1241202408781.shtm](http://www.dhs.gov/files/programs/gc_1241202408781.shtm). A link to this information is also prominently placed on the DHS Intranet, DHS Online.

Components issued additional implementation guidance within their organizations, as well. For example, on August 19, 2009, Gale Rossides, the TSA Acting Administrator issued a memo (attached) stating that TSA would follow the Department's guidance for voluntary respiratory protection use referencing Under Secretary Duke's memo and further stating that "If you want to wear a mask, TSA will make both N95 respirators and surgical masks available to you."

<b>Question#:</b>	3
<b>Topic:</b>	PPE
<b>Hearing:</b>	H1N1 Flu: Monitoring the Nation's Response
<b>Primary:</b>	The Honorable Daniel K. Akaka
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

TSA developed a document of Frequently Asked Questions (FAQs). This document is available to all employees on the TSA homepage. It provides specific guidance to employees regarding how they can obtain respiratory protection for voluntary use. A copy of the FAQs is attached.

Employees who choose to use respiratory protection on a voluntary basis must receive a copy of the Appendix D to 29 CFR 1910.134. This is a mandatory requirement of the Occupational Safety and Health Administration and applies specifically to voluntary use of respiratory protection equipment. This is in no way intended to be an impediment to voluntary respiratory protection equipment use. A copy of the form is available to TSA employees and was distributed with the FAQs.

At this time, DHS is not aware of any remaining issues regarding respiratory protection availability. There have been some cases of employees wearing respirators around their necks or hanging them off their uniforms. These practices are not permitted. These actions make the respirators more accessible to employees, but also allow the inside of the device to be exposed to materials throughout the day, thus negating their protective value. These issues are currently being addressed by TSA to help employees identify solutions. The wearing of masks around the neck or hanging them on a uniform is specifically addressed in the FAQs

**Question:** What information are employees provided about PPE and how to obtain it?

**Response:** Guidance for PPE use is available on the DHS public web page as well as on the DHS Intranet. Due to the varying missions and widely dispersed DHS workforce, the operational level distribution of protective equipment is managed at Component and local levels. This ensures equipment is readily accessible to employees.

**Question:** For employees who wear PPE, how do you ensure that they are properly donning and utilizing the equipment?

**Response:** Basic information on respiratory use is available through the DHS Internet and Intranet web pages.

Employee guidance for voluntary use of respirators contains the following information which establishes minimum requirements and use limitations:

“DHS employees choosing to voluntarily wear N-95 respirators as a precaution should be aware of the proper use and limitations of respirators. Before wearing an N-95 respirator, consider the following:

<b>Question#:</b>	3
<b>Topic:</b>	PPE
<b>Hearing:</b>	H1N1 Flu: Monitoring the Nation's Response
<b>Primary:</b>	The Honorable Daniel K. Akaka
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

- Use only a National Institute for Occupational Safety and Health (NIOSH) approved respirator; a NIOSH approval label will appear on or in the respirator packaging.
- Read and follow all instructions provided by the manufacturer about the use, maintenance, and warnings regarding the respirator's limitations.
- Use an N-95 only for tasks that have been evaluated as appropriate by a safety and health professional.
- Only one person should use a single N-95 respirator; do not share respirators.

In addition, a separate guidance document was developed and is available at "[Fit Checking Guidance for Voluntary Use of a Respirator.](#)"

Employees who are required to wear respiratory protective equipment receive training on properly donning and utilizing the equipment. They are also medically evaluated and fit-tested in accordance with safety and health requirements. Further guidance is posted on the DHS website, [Fit Testing Guidance for Mandatory Use of Respirators.](#)

<b>Question#:</b>	4
<b>Topic:</b>	software
<b>Hearing:</b>	H1N1 Flu: Monitoring the Nation's Response
<b>Primary:</b>	The Honorable Thomas R. Carper
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:** I have had brought to my attention a software that models disease spread developed through the Office of Naval Research. This software was used successfully by ONR and HHS in evaluating the effectiveness of various responses to the spring 2009 H1N1 flu outbreak in Mexico and the Southern Hemisphere, including supporting decisions made by US Northern Command and HHS such as whether to close the US Mexico border.

As a former governor, I can see the usefulness of this software for mayors and governors, whose public health staff must develop the appropriate responses to the H1N1 flu that is breaking out across the US.

As the cabinet agencies on the front lines of responding to the current outbreak, are you aware of this technology developed through ONR? If so, has the federal government given thought to making it available to cities and states to enable them to develop the most appropriate response to the outbreaks?

**Response:** DHS is aware that the government and the private sector have developed technologies that model the spread of disease. The Department of Homeland Security (DHS) works closely with the National Labs and others to apply available models to analyze economic and critical infrastructure impacts of pandemic influenza. With regards to H1N1 Pandemic Modeling and impact analysis on critical infrastructures, DHS and the Department of Health and Human Services (HHS) continue to work collaboratively on the development of modeling technology, specific software applications and the analysis of model output. As models become available, DHS reviews technologies, and in collaboration with other Federal Agencies such as HHS, evaluates whether they could be beneficial to support state and local planning efforts. The Centers for Disease Control and Prevention (CDC) has several tools designed to assist state and local level planners in estimating the potential impacts of pandemic influenza specific to their locality. In particular, some of the tools available at the CDC website are: FluAid 2.0 (<http://www.cdc.gov/flu/tools/fluaid/>), Community Flu 1.0 (<http://www.cdc.gov/flu/tools/communityflu/>), and FluSurge 2.0 (<http://www.cdc.gov/flu/tools/flusurge/>).

<b>Question#:</b>	5
<b>Topic:</b>	technology
<b>Hearing:</b>	H1N1 Flu: Monitoring the Nation's Response
<b>Primary:</b>	The Honorable Thomas R. Carper
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:** As we face a nation-wide H1N1 outbreak, does the federal government currently have technology that allows policymakers to accurately predict the effectiveness of different measures such as closing schools, wearing facemasks, etc.?

**Response:** A wide range of researchers across government and the academic community, both in the U.S. and internationally, have been examining these issues for many years. While it is not possible to predict with complete accuracy the specific effects of various mitigation measures, the scientific community can utilize the best available information in order to assist in the development of pandemic preparedness plans. As a pandemic such as H1N1 progresses, decision makers at all levels can then use evolving science to inform changes in plans. My senior health and medical advisors have continued to keep DHS leadership informed of the latest information available from across the scientific community.

At my direction, DHS is actively involved with Federal partners, national laboratories, and private sector partners in using models related to the current 2009-H1N1 influenza pandemic. Shortly after 2009-H1N1 was identified in April, 2009, the Office of Health Affairs (OHA), through the National Biosurveillance Integration Center (NBIC) engaged the National Infrastructure Simulation and Analysis Center (NISAC) to coordinate and run a first set of models to assess potential impacts on critical infrastructure and key resource (CIKR) sectors during the oncoming fall flu season. The first modeling effort identified a number of probable trends including:

- Healthcare system will experience a shift in demand for services (hospitalization of younger individuals as opposed to seasonal flu which affects elderly populations more severely);
- Economic and sector impact
  - At its peak, flu-related worker absenteeism is expected to be about double the normal flu season (3%);
  - Normal absenteeism rate of industry of 7% -- absenteeism rate is expected to be no more than 15-20% nationally if schools are closed, necessitating worker absence to care for children ;
  - Nationally, the impact to the U.S. economy is expected to be well less than 1% of the GDP.
- Mitigating measures, particularly deployment of an H1N1 specific vaccine, could significantly reduce the number of infected people.

<b>Question#:</b>	5
<b>Topic:</b>	technology
<b>Hearing:</b>	H1N1 Flu: Monitoring the Nation's Response
<b>Primary:</b>	The Honorable Thomas R. Carper
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

A second series of model runs is currently in progress utilizing revised H1N1 disease characteristics. Revised H1N1 disease characteristics were developed based on the availability of better epidemiological data (as more countries such as those in the southern hemisphere and Australia reported H1N1-2009 data collected/disease observations and CDC's spring observations/assessment of H1N1-2009 in the United States). This second series of model runs are under the direction of a joint team from the DHS/Office of Health Affairs (OHA), the Department of Health and Human Services/Assistant Secretary for Preparedness and Response (ASPR) and the Centers for Disease Control and Prevention (CDC). These second model runs are expected to yield more refined results and will provide a comparative baseline of how various models operate that could be used in tandem in the future.

<b>Question#:</b>	6
<b>Topic:</b>	antivirals
<b>Hearing:</b>	H1N1 Flu: Monitoring the Nation's Response
<b>Primary:</b>	The Honorable Thomas R. Carper
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:** I wanted to follow up on Chairman Lieberman's request on the "over order" of IV antivirals. What is the right number of courses we need to ensure that doctors across the country have immediate accessibility to these IV antivirals that can help save the lives of some of our most critical patients suffering from H1N1?

**Response:** Intravenous antivirals are one of many tools healthcare providers use to treat 2009-H1N1. On October 23, 2009, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for intravenous peramivir to treat 2009-H1N1. This EUA allows for the use of intravenous peramivir in certain hospitalized patients with suspected or laboratory confirmed 2009-H1N1. All operational planning for the distribution and use of intravenous peramivir is being managed by the Department of Health and Human Services and DHS defers to our colleagues at HHS to discuss this issue further. DHS stands ready to provide any logistical support needed and will respond to requests for assistance on the part of states and territories.

<b>Question#:</b>	7
<b>Topic:</b>	assistance
<b>Hearing:</b>	H1N1 Flu: Monitoring the Nation's Response
<b>Primary:</b>	The Honorable Susan M. Collins
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:** One of the failures our Committee found during our investigation of the response to Hurricane Katrina was the belief by many in the federal government that federal assistance for responding to a natural disaster could only be provided after a state had failed at its efforts to respond effectively. As we saw, such a policy had disastrous results, since this often meant that federal assistance arrived much too late. As we prepare for an H1N1 pandemic, I remain concerned that your department is not taking a sufficiently proactive approach to anticipating where gaps might be at the state and local levels and addressing those gaps early.

DHS should be working closely with state public health and emergency management offices to provide hands-on federal assistance now, rather than waiting for states or localities to falter.

What specific steps is your department taking to provide this much needed assistance proactively to those who need it?

**Response:** DHS has taken an aggressive, proactive approach to the response to 2009 H1N1. FEMA Regions have hosted H1N1 seminars and interagency conference calls with state and local emergency management partners. The intent is to maintain full situational awareness of emerging shortfalls and requirements.

FEMA's Disaster Assistance Directorate has developed procedures and criteria, under the authority provided in the Stafford Act, outlining how state and local governments request assistance from the federal government. The FEMA guidance, titled "Procedure for Evaluating State Requests for Emergency Disaster Declarations for Pandemic Influenza," is designed to provide states information on factors considered in evaluating state requests for emergency assistance declarations for a pandemic influenza. In addition, FEMA Public Assistance developed a Disaster Assistance Fact Sheet, entitled "2009 H1N1 Influenza Frequently Asked Questions."

FEMA has staffed and trained 56 Incident Management Assistance Teams-Advance (IMAT-As) to provide direct federal support to any state or territory upon a governor's request. The primary mission of an IMAT-A is to rapidly deploy to an incident or at-risk venue, provide leadership in the allocation and provision of federal assistance, and to coordinate and integrate an inter-jurisdictional response in support of the affected state(s) or U.S. territory(s). The IMAT-As will: support efforts to meet the emergent needs of

<b>Question#:</b>	7
<b>Topic:</b>	assistance
<b>Hearing:</b>	H1N1 Flu: Monitoring the Nation's Response
<b>Primary:</b>	The Honorable Susan M. Collins
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

state and local jurisdictions; possess the capability to provide initial situational awareness for federal decision-makers; and support the initial establishment of a unified command. Last month, FEMA activated the National IMAT East to provide a dedicated coordination cell for the 2009 H1N1 national response.

FEMA's Mass Care Unit is working with state, regional, federal, and non-governmental organization partners in the development of a Mass Care (ESF6)/Emergency H1N1 Planning Guidance Template that will assist states with planning for sheltering, feeding operations and donations management within an H1N1 environment. The Mass Care/Emergency Assistance Planning Guidance Template will provide guidelines for the FEMA regions to support states in their planning efforts for either a pandemic or a pandemic combined with a natural or man-made disaster.

DHS also offers training for state, territory, local and tribal homeland security and emergency management professionals. Interested partners may take the Center for Domestic Preparedness (CDP) revised Pandemic Influenza Planning and Preparedness (PIPP) course to learn new information and updated planning considerations for the 2009 H1N1 strain.

Finally, FEMA's Individual Assistance's Crisis Counseling Program (CCP) is also working with HHS' Single State Medicaid Agencies (SMSA) to develop a contingency plan for administering CCP technology in the event of a mass infectious disease outbreak.

DHS has been in constant communication with our intergovernmental stakeholders as well. DHS Intergovernmental Programs (IGP) has participated in multiple calls, along with HHS Intergovernmental Affairs (IGA) and White House IGA with Mayors across the country, as well as a call with DHS IGP, HHS IGA and White House IGA with Governor's Chiefs of Staffs. IGP continues to conduct bi-weekly conference calls with State Homeland Security Advisors (HSAs), Emergency Managers, and Adjutants General.

<b>Question#:</b>	8
<b>Topic:</b>	scanners
<b>Hearing:</b>	H1N1 Flu: Monitoring the Nation's Response
<b>Primary:</b>	The Honorable Susan M. Collins
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:** During our last hearing on H1N1, I asked you about the possible use of thermal scanners to screen the 400 million people that come across our borders each year for indications of illness. At that time, you stated that you did not believe that these scanners were effective at detecting travelers that have elevated temperatures, which could be one indicator of H1N1 or, for that matter, any other future potential pandemic. However, Singapore, Thailand, Japan, Indonesia, South Korea, and the Philippines still deploy thermal scanners at their airports, and now Australia has also deployed them.

Although not all elevated temperatures can be attributed to the flu and not all travelers with the flu have a fever, no single border security measure is 100 percent effective. That is why we have layers of security and provide CBP officers at the border with multiple tools for determining whether someone should be denied entry or quarantined.

Wouldn't deploying this type of technology at least give CBP officers a starting point when questioning people crossing our borders that they could employ to varying degrees depending on the volume of passengers and information about the prevalence of H1N1 in the country from which travelers are arriving?

**Response:** At this time, screening travelers coming into or out of the U.S. would result in no public health benefit since 2009-H1N1 is reported in more than 100 countries across the globe. In addition, the World Health Organization (WHO) does not recommend entry or exit screening because the virus has already been confirmed in many parts of the world.

To obtain information on the prevalence of H1N1 in the U.S., the Centers for Disease Control and Prevention (CDC) continues to aggressively conduct surveillance. CDC also actively monitors for changes in the epidemiology of the 2009-H1N1 flu virus. In addition, the Federal government has focused its efforts on slowing the spread of 2009-H1N1 within communities by communicating health information and infection control messages and recommending that, when people are sick, they stay home and do not travel.

<b>Question#:</b>	9
<b>Topic:</b>	impact
<b>Hearing:</b>	H1N1 Flu: Monitoring the Nation's Response
<b>Primary:</b>	The Honorable Lindsey O. Graham
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:** What concerns do you have, if any, regarding the impact on continuity of operations and protection of critical infrastructure if we don't have sufficient stockpiles of both vaccinations and treatments available for first responders?

**Response:** Depending on the severity of the pandemic, if there is an insufficient stockpile of vaccine and treatment for first responders to protect and treat 2009-H1N1, there could be impacts on continuity of operations and protection of critical infrastructure. The first responder community will likely see the same levels of absenteeism as the general population, and therefore a reduction in the number of first responders available for duty could affect day to day operations.

DHS will continue to work to support our state, regional, local, and tribal responders and ensure they have the guidance and resources necessary to fulfill their critical mission. DHS Homeland Security Grant Program (HSGP) funding can be used by recipients to purchase antiviral treatments.

<b>Question#:</b>	10
<b>Topic:</b>	funding
<b>Hearing:</b>	H1N1 Flu: Monitoring the Nation's Response
<b>Primary:</b>	The Honorable Lindsey O. Graham
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:** Does DHS plan to encourage States to consider utilizing funding they receive through the State Homeland Security Grant Program, the Urban Area Security Initiative, or the Metropolitan Medical Response System Program to purchase antivirals for Mass Prophylaxis efforts?

**Response:** The Department of Homeland Security's (DHS) grant programs currently allow for the purchase of pharmaceuticals, including antibiotics and antivirals. In addition, one of the national priorities noted in the FY 2009 Homeland Security Grant Program (which includes State Homeland Security Program, the Urban Areas Security Initiative and the Metropolitan Medical Response System) was "Medical Surge and Mass Prophylaxis." Under this priority, State and local grantees should consider preparedness efforts that emphasize biological attack detection (bio collection), mass casualty incident response, and counter-measure stockpiling and distribution.

<b>Question#:</b>	11
<b>Topic:</b>	TCL
<b>Hearing:</b>	H1N1 Flu: Monitoring the Nation's Response
<b>Primary:</b>	The Honorable Lindsey O. Graham
<b>Committee:</b>	HOMELAND SECURITY (SENATE)

**Question:** The Target Capabilities List suggests that states take several actions to protect the health of the U.S. population by developing the procedures for the distribution and dispensing of mass prophylaxis; and developing processes to ensure that first responders, public health responders, critical infrastructure personnel, and their families receive prophylaxis. Does DHS know how many states have established these procedures? What role does DHS have to ensure these procedures are in place before a public health emergency?

**Response:** The facilitation and monitoring of State capabilities to receive, secure, prioritize, and distribute medical countermeasures is the responsibility of the Centers for Disease Control and Prevention's (CDC) Office of Public Health Preparedness and Response (formerly Coordinating Office for Terrorism Preparedness and Emergency Response (COTPER)), which manages the Strategic National Stockpile (SNS). The CDC recently published a report on state and local readiness titled: "Public Health Preparedness: Mobilizing State by State" (February 20, 2008). This Report highlights the progress that has been made in state and local preparedness and response, identifies preparedness challenges facing public health departments, and outlines CDC's efforts to address those challenges. This Report can be found at <http://emergency.cdc.gov/publications/feb08phprep/>. CDC plans to release its next report on state preparedness in February 2010. At present, all 62 project areas funded under the CDC Public Health Emergency Preparedness Cooperative Agreements have plans in place to respond to public health emergencies, including the capability to receive, distribute, and dispense medical countermeasures in a bioterrorism event.

The Department of Homeland Security (DHS) works closely with the Department of Health and Human Services (HHS) to develop and update the public health Target Capability on 'Mass Prophylaxis' to ensure consistency among the different preparedness programs.



## Homeland Security

Aug. 17, 2009

MEMORANDUM FOR: All DHS Employees

FROM: Elaine C. Duke  
Under Secretary for Management

SUBJECT: Guidance Documents Regarding Novel H1N1 Flu Virus

In preparation for the start of the flu season this fall, DHS has developed a series of guidance documents for the DHS workforce about the H1N1 Flu Virus. These documents are designed to provide guidance to both employees and supervisors on actions we all can take to prepare and plan for a probable return of the H1N1 virus this fall.

The guidance covers a number of important topics and a variety of situations, such as the use of Personal Protective Equipment and antivirals. Based on the best available information from the Centers for Disease Control and Prevention, as well as valuable input from DHS components, this guidance also covers leave policies, teleworking, and alternative work schedule arrangements for employees who are ill themselves or serving as caregivers for sick family members. The guidance documents have been uploaded for easy access to the DHS public Web site at [http://www.dhs.gov/files/programs/gc\\_1241202408781.shtm](http://www.dhs.gov/files/programs/gc_1241202408781.shtm).

Secretary Napolitano and I, along with all DHS leadership, are committed to providing you with the best guidance — which will always be based on the latest scientific understanding about H1N1 — and we will continue to keep you apprised of the latest developments. We also encourage all of you and your families to take steps to help prevent the spread of this virus. These steps and the latest information about the H1N1 virus are available at <http://www.flu.gov/>.

# H1N1 Flu Information



## Frequently Asked Questions for TSA Employees

### What's the big deal about H1N1?

H1N1 is a flu virus that causes illness ranging from mild to severe. In June 2009, the virus reached pandemic levels, which means that cases of H1N1 are occurring in multiple places at the same time. Many people who have become ill with H1N1 have recovered without requiring medical treatment. However, hospitalizations and deaths have occurred. In addition to H1N1, seasonal flu viruses will also likely cause illness this fall and winter. For more information about how to help keep yourself from getting H1N1, prevent spreading H1N1 and to learn what to do if you are exhibiting flu-like symptoms, please visit [www.http://www.flu.gov/](http://www.flu.gov/)

### Is this the same as swine flu?

According to the CDC, the H1N1 virus was originally referred to as "swine flu."

I interact with the public every day. Am I going to catch H1N1? How would I catch it? Spread of the H1N1 virus is thought to occur in the same way that the seasonal flu spreads. Flu viruses are mainly spread from person to person through coughing or sneezing by people with influenza. Sometimes people become infected by touching something with flu virus on it and then touching their mouth or nose. For more information please visit [www.http://www.flu.gov/](http://www.flu.gov/)

### What is TSA doing to protect me on the front line?

TSA offers free annual seasonal flu immunizations to all employees and plans to offer the H1N1 immunization as soon as the vaccine becomes available. In addition, TSA has purchased and distributed alcohol-based hand sanitizer to the field and we continue to provide nitrile gloves for employees to wear while at work. Also, any employee on the frontline who wants to wear a mask can do so. TSA is making both surgical masks and N95 respirators available to those who wish to wear them.

### Can I wear a mask while at work? Which kinds will be available to me?

Employees can wear a mask if they choose to. TSA is making both surgical masks and N95 respirators available to TSA employees.

### How long does one mask last? Do they expire?

Both surgical masks and N95 respirators are designed to be single use and are disposable. You should discard a surgical mask or N95 respirator if it becomes wet, soiled, or damaged. Unused masks and N95 respirators do not have expiration dates.

# H1N1 Flu Information

If I choose to wear a surgical mask, how many do I get and who will give them to me?

If you choose to wear a surgical mask or N95 respirator, you should request one from your supervisor. The masks and N95 respirators will be issued one at a time as needed.

Do I still need to take the N95 training?

Because TSA employees' use of the N95 respirator is voluntary at this time, you will not be required to undergo a medical evaluation, a fit test, or a written respiratory protection program if you choose to use it instead of a surgical mask. Nevertheless, TSA is recommending that all employees take the OLC N95 training so that if in the future you are required to wear an N95 respirator you are prepared to do so. The training is designed to increase awareness about the N95 respirator and to instruct you on how to wear it correctly.

Prior to wearing the N95 respirator, you must be provided the manufacturer's fitting instructions for the N95 respirator (model 8210 and model 1860), and be instructed to dispose of the N95 respirator if it is damaged or soiled, or if breathing becomes difficult while wearing it.

If you choose to wear the N95 respirator, you must read and sign the attached Appendix D to Sec. 1910.134 (Mandatory), Information for Employees Using Respirators When Not Required Under the Standard.

If you choose to wear a surgical mask, there is no training needed.



October 23, 2009

If I wear a mask, am I supposed to wear it all day? Or can I hang the mask from my belt or around my neck?

Both surgical masks and N95 masks are disposable and designed to be worn as single-use masks. You may choose to wear a surgical mask or N95 all day. Nevertheless, you should dispose of it when you are finished performing the task for which you decided to wear the mask. When employees no longer wish to wear the mask, they should discard it in a trash receptacle. They should neither be worn loosely around the face and neck nor attached to uniform items. Both the surgical masks and respirators should be replaced if they become wet, soiled, or damaged.

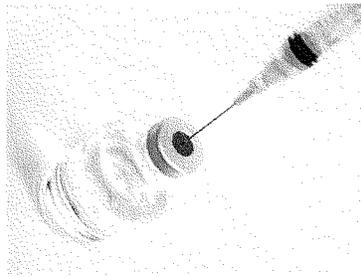
Can we dispose of the ETD swabs after their use on CPAP machines to limit the risk of flu infection and transmission?

ETD swabs must be disposed of after being used on CPAP machines. They should also be disposed of whenever they are used to test any type of breathing apparatus.

Will TSA get flu shots for us? When? What about my family members?

TSA will offer the annual seasonal flu vaccination to all federal TSA employees as usual. We will also offer the H1N1 vaccination to employees when the vaccine becomes available to the federal workforce. We anticipate that we will receive the seasonal flu vaccine from Federal Occupational Health in October. The CDC has indicated that the H1N1 vaccine will first be available in the middle of October. It is recommended that those that are at high risk for getting H1N1 – pregnant women, people with underlying health conditions and health care workers should be the first ones to get the

# H1N1 Flu Information



H1N1 vaccine. For more information on the H1N1 vaccine please visit <http://www.flu.gov/> At the present time, TSA only provides flu immunizations for our federal employees.

**What will happen if I am told to stay home or go home by my supervisor or manager? Will I be charged sick time, annual leave, or LWOP?**

If you are ill, have flu-like symptoms (fever, headaches, fatigue, achiness, body aches, nausea or vomiting), or need to care for an ill family member, you should remain at home. The CDC recommends that you stay home from work and limit contact with others to avoid infecting them. According to the <http://www.flu.gov/> Web site, in the current flu conditions, students and staff with symptoms of flu should stay home for at least 24 hours after they no longer have fever or do not feel feverish, without using fever-reducing drugs. If the flu conditions become more severe, CDC recommends that a sick person stay home for 7 days.

October 23, 2009

You may use sick leave, annual leave, compensatory time off, or LWOP when ill or when caring for an ill family member. You may also request advanced sick leave and annual leave within established policy provisions to cover the absences. Employees who have exhausted available leave may apply to become a leave recipient under the Voluntary Leave Transfer Program (VLTP) for personal illness or to care for ill family members.

Prior to making any determination to send an employee home, the appropriate management official must consult with a member of the Employee Relations staff at HQ.

**What if I am on leave restriction or have other discipline pending?**

Employees on leave restriction should follow the procedures for requesting leave as outlined in the letter of leave restriction.

**What if my child is told to stay home from school or the school district closes? What are my leave options?**

There can be more than one circumstance that results in children being told to stay home from school. The leave options available to employees will be determined by the circumstances as described below.

Under all of the circumstances described below, an employee may choose from the following options:

- Annual leave
- Compensatory time off
- Request advanced annual leave within established policy provisions
- Leave Without Pay (LWOP).

# H1N1 Flu Information

## Circumstance 1:

The child is well and available information indicates the child has not been exposed to the virus. The employee may choose from the leave options described above.

## Circumstance 2:

The child is well and available information indicates the child has been exposed to the virus. The child was sent home from school and the school sent home a letter signed by a representative from a government health department advising parents that all of the children in his/her classroom have been exposed to the virus and may be contagious.

When a relevant health authority or health care provider has determined a family member's presence in the community may jeopardize the health of others because of exposure to a communicable disease, you may use, in addition to the leave options listed above, sick leave to care for the family member. Sick leave for this purpose is considered to be general family care and employees are limited to using up to 104 hours of sick leave for this purpose in a leave year. Employees may also request advanced sick leave within established policy provisions.

## Circumstance 3:

The child is ill. All of the options outlined above, including sick leave, are available. Employees may also request advanced sick leave within established policy provisions. In addition, employees who have exhausted available leave may apply to become a leave recipient under the Voluntary Leave Transfer Program (VLTP) to care for ill family members.

A note on telework: If you are not a mission essential employee, your manager may consider

allowing you to work from home. Working from home is dependent upon the employee's duties, availability of necessary equipment, and computer and communication connectivity. Telework is not an option if the employee is providing dependent care; employees providing direct care are unable to perform work at the same time. However, employees approved for telework may use a combination of leave and telework to provide needed care and accomplish work assignments.

Finally, please remember that there are several things that you can do to protect yourself. These include:

- Cover your nose and mouth with a tissue when you cough or sneeze.
- Throw the tissue in the trash after you use it.
- Wash your hands often with soap and water.
- Alcohol based hand sanitizers are also effective. Avoid touching your eyes, nose, and mouth. Germs are often spread this way.
- Stay home if you are sick.
- Keep commonly used surfaces clean by wiping them down with a household disinfectant according to the directions on the product label.
- Keep your immune system healthy by getting plenty of rest, eating a well-balanced diet, managing your stress, and exercising regularly.

Visit <http://www.flu.gov/> and TSA's H1N1 iShare page [https://ishare.tsa.dhs.gov/Offices/StratCommPubAffairs/Pages/h1n1\\_information.aspx](https://ishare.tsa.dhs.gov/Offices/StratCommPubAffairs/Pages/h1n1_information.aspx) for more information.

October 23, 2009

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**From:** TSABroadcast  
**Sent:** Wednesday, August 19, 2009 3:22 PM  
**Subject:** 100 – Information for Frontline Workforce on DHS H1N1 Guidance

**Date:** August 19, 2009  
**To:** All Field Employees  
**From:** Gale Rossides  
Acting Administrator  
  
Lee Kair  
Assistant Administrator for Security Operations  
**Subject:** 100 – Information for Frontline Workforce on DHS H1N1 Guidance

The Department reissued guidance for mask usage related to the H1N1 flu on Monday, August 17 and TSA will follow that guidance. This guidance continues to place TSOs and FAMs in the medium risk category, which means they are not required to wear masks when interacting with passengers on a regular basis. If you want to wear a mask, TSA will make both N95 respirators and surgical masks available to you. We currently have N95s on hand and we are in the process of purchasing and distributing surgical masks to the field. Wearing the surgical mask requires no additional training or medical evaluation.

There is no medical clearance, training, or fit testing for voluntary use of either the N95s or surgical masks. But, to ensure that employees use the PPE properly and in the event that we come to a mandatory use in the future, TSA is rolling out training and a N95 respirator use program to medically clear and fit test employees.

Thank you for your continued commitment to our mission and one another.



## Fit Checking Guidance for Voluntary Use of a Respirator

*Using a respirator makes your lungs and heart work harder. A medical evaluation is not required to voluntarily wear an N-95 respirator on the job. However, if you have a medical condition that might preclude the use of a respirator, you should consult with your physician.*

To ensure respirators are providing the intended level of protection, they should be "fit checked" each and every time they are worn. To fit check a respirator, the wearer should forcefully inhale and exhale several times. The respirator should collapse slightly upon inhaling and expand upon exhaling. The wearer should not feel any air leaking between his/her face and the respirator. This is the sign of a good facial fit and a successful fit check.

If the respirator does not collapse and expand, OR if air is leaking out between the wearer's face and the respirator, then this is NOT a good facial fit. The wearer should adjust the respirator until the leakage is corrected and he/she is able to successfully fit check the respirator.

**Note:** Fit checking is NOT a substitute for fit testing. Fit checking is a simple procedure intended to help the wearer verify that he/she has properly donned the respirator. Fit testing is designed to determine the appropriate size respirator for each wearer.

### Tips for Achieving a Good Fit

If the wearer is having a problem successfully fit checking the respirator, he/she should try the following tips:

1. Use a mirror while adjusting the respirator.
2. Ask someone to look for hair or earrings that might be caught in the seal.
3. Make sure the headbands are positioned properly. It is especially important that the top headband is on the crown of your head, as it is designed to hold the bottom of the respirator snug against your chin.

**Note:** The respirator should be fit checked each and every time it is donned.

Employees may request an accommodation with regard to use of respirators by contacting the Office of Civil Rights and Civil Liberties.

Read OSHA's interpretation of the standard concerning facial hair:  
[2/06/2006 - Facial hair and voluntary use of filtering facepiece respirators.](#)

An employer must provide the following information to any employee or volunteer who uses an employer-provided respirator voluntarily or provides his or her own respirator:  
[\(Mandatory\) Information for Employees Using Respirators When Not Required Under the Standard - Appendix D to Sec. 1910.134](#)

*This document provides general guidance only for employees covered by Title 5, United States Code, and does not, and is not intended to create or violate any legal rights.*

This page was last reviewed/modified on September 10, 2009.



## Fit Testing Guidance for Mandatory Use of Respirators

*Using a respirator may place a physiological burden on employees that varies with the type of respirator worn, the job and workplace conditions in which the respirator is used, and the medical status of the employee. Before an employee may be required to use any respirator, the employee must be evaluated to determine that they are medically able to wear the respirator. The Occupational Safety and Health Administration (OSHA) requires that a medical evaluation be performed to determine an employee's ability to use a respirator, before the employee is fit tested or required to use a respirator in the workplace.*

Use of a respirator requires proper fit testing, OSHA's Fit Testing procedures are specified in Appendix A of 1910.134 - Fit Testing Procedures (Mandatory).

Fit Testing may be quantitative or qualitative. The individual performing the Fit Test procedure requires no special certification. However, the individual must be able to prepare the test solutions, calibrate the equipment and perform the tests properly, recognize invalid tests, and ensure that test equipment is in proper working order. The ability to calculate fit factors is also a requirement for the individual administering a Quantitative Fit Test.

Specific Fit Testing procedures will vary depending on which respirator is selected, whether a quantitative or qualitative protocol is used, and other factors. The following provides general guidance on Qualitative Fit Testing procedures for the use of a NIOSH-certified N95 filtering facepiece respirators.

### Directions for Proper Donning

Proper donning of an N95 filtering facepiece respirator may feel a little awkward at first, but it will become easier with repeated applications. The following instructions should be followed when donning fold flat respirators (see manufacturer's instructions for other respirator models):

1. Separate the edges of the respirator to fully open it.
2. Slightly bend the metal nosepiece to form a gentle curve.
3. Hold the respirator upside down to expose the two headbands.
4. Using your index fingers and thumbs, separate the two headbands.
5. While holding the headbands with your index fingers and thumbs, cup the respirator under your chin.
6. Pull the headbands up over your head.
7. Release the lower headband from your thumbs and position it at the base of your neck.
8. Position the remaining headband at or near the crown of your head.
9. Conform the nosepiece across the bridge of your nose by firmly pressing down with your fingers.
10. Continue to adjust the respirator and secure the edges until you feel you have achieved a good facial fit. Now, perform a Fit Check.

### Directions for Performing a User Seal Check

To ensure N95 filtering facepiece respirators are providing the intended level of protection, a "User Seal Check" MUST be performed each and every time they are worn.

To Seal Check a respirator, the wearer should forcefully inhale and exhale several times. The respirator should collapse slightly upon inhaling and expand upon exhaling. The wearer should not feel any air leaking between his/her face and the respirator. This is the sign of a good facial fit and a successful Seal Check.

If the respirator does not collapse and expand OR if air is leaking out between the wearer's face and the respirator, then this is NOT a good facial fit. The wearer should adjust the respirator until the leakage is corrected and he/she is able to successfully perform a User Seal Check with the respirator.

**Note:** A User Seal Check is NOT a substitute for Fit Testing. A User Seal Check is a simple procedure intended to help the wearer verify that he/she has properly donned the respirator. Fit Testing is designed to determine that an appropriate size respirator and an adequate fit has been achieved for each wearer.

### Tips for Achieving a Good Fit

If the wearer is having a problem successfully performing a User Seal Check with the respirator, he/she should try the following tips:

1. Use a mirror while adjusting the respirator.
2. Make sure the headbands are positioned properly. It is especially important that the top headband is on the crown of your head, as it is designed to hold the bottom of the respirator snug against your chin.
3. **Note:** It is important to stress to the wearer that:
  - o The respirator must be User Seal Checked each and every time it is donned, and
  - o He/she should not proceed with activities until a successful Fit Check has been completed.

### Qualitative Fit Testing Protocol

This guidance provides instruction on Qualitative Fit Testing using the Bitrex™ method. The Qualitative Fit Testing protocol consists of two parts: a Threshold Check and a Fit Test. The Threshold Check determines the subject's ability to taste a weak solution of the challenge agent.

1. Pour the contents of Threshold Check Solution into the Threshold Check nebulizer. Prepare the Fit Test nebulizer with the Fit Test Solution in the same manner.
2. Assemble the hood by pressing the VELCRO® strips together and fitting the bouffant cap over the top, securing the seam of the cap under the tabs on the hood.
3. The Fit Test protocol should be explained to the test subject prior to testing. The test subject should not eat, chew gum, or drink anything but water for at least 15 minutes prior to the test.
4. Record the name of the test subject, type of respirator (N95), brand and size of respirator, and date of the test.

### Threshold Check Procedure

1. Have the test subject put on the hood without a respirator.
2. Instruct the subject to breathe normally with his/her mouth open.
3. Instruct the subject to immediately report when the challenge agent is tasted.
4. Insert the nozzle of the Threshold Check nebulizer into the hole at the front of the hood being sure to point the nebulizer away from the nose and mouth area. Squeeze the bulb firmly ten times. (If the person reports a taste during this process, stop squeezing. Record "10" as the number of squeezes required, regardless of when the person reported the taste.)
5. If the subject has not tasted the solution, administer another 10 squeezes. (If the person reports a taste during this process, stop squeezing. Record "20" as the number of squeezes required, regardless of when the person reported the taste.)
6. If the subject has not tasted the solution, administer another 10 squeezes and ask again if they have tasted the solution. (If the person reports a taste during this process, stop squeezing. Record "30" as the number of squeezes required, regardless of when the person reported the taste.)
7. If no taste has been detected, and if saccharin is being used, then the subject should be tested with the alternative BITREX® solution using these same procedures. If the subject is unable to taste either saccharin or BITREX®, then the subject cannot be tested using this protocol. Instead, quantitative Fit Testing is suggested.
8. Remove the hood and allow the subject to rinse his/her mouth with water and wipe his/her face. The subject should not proceed to the Fit Test until the taste of the challenge agent has been allowed to clear, which usually takes several minutes.

### Fit Test Procedure

1. Have the subject put on the respirator and perform a User Seal Check. The subject should be allowed to wear the respirator for at least five minutes prior to beginning the fit test, adjusting it as needed.
2. Place the hood on the subject, making sure that there is sufficient room for the subject to move his/her head from

- side to side and up and down without the mask touching the sides of the hood.
3. Instruct the subject to breathe through his/her open mouth for the duration of the test and to report if the taste of the solution is detected at any time during the test.
  4. Insert the nozzle of the Fit Test nebulizer into the hole at the front of the hood, pointing it away from the nose and mouth, and spray 10, 20, or 30 squeezes into the hood, depending on which number was recorded from the Threshold Check.
  5. Maintain the aerosol concentration in the hood throughout the test by squeezing one half the initial number of squeezes every 30 seconds into the hood.
  6. Instruct the subject to perform the series of exercises below for 60 seconds each:
    - o Normal Breathing
    - o Deep Breathing
    - o Turning head from side to side (pausing for a breath when head is to side)
    - o Moving head up and down slowly (pausing for a breath while head is up)
    - o Talking (reading the enclosed "Rainbow Passage," reciting the alphabet, etc.)
    - o Grimace (smiling or frowning) for 15 seconds
    - o Jogging in Place
    - o Normal Breathing
  7. If the exercises are completed without the subject tasting the aerosolized solution, then an acceptable fit has been demonstrated and the subject has passed the test.
  8. If the subject reported tasting the aerosolized solution during the test, then the subject has failed to achieve an acceptable fit. The test subject should be allowed to re-test with the same model respirator or with another model respirator of his/her choice. Wait at least 15 minutes before re-testing and begin by repeating the Threshold Check.

## Cleaning-Up

1. Rinse the nebulizers with warm water to prevent clogging.
2. Wipe out the inside of the hood with a damp cloth or paper towel to remove any solution residue. A disinfectant, such as isopropyl alcohol, may be used for cleaning to reduce potential contamination.

*This document provides general guidance only for employees covered by Title 5, United States Code, and does not, and is not intended to create or violate any legal rights.*

This page was last reviewed/modified on August 17, 2009.

**Post-Hearing Questions for the Record  
Submitted to the Honorable Kathleen Sebelius  
From Senator Joseph I. Lieberman**

**“H1N1 Flu: Monitoring the Nation’s Response”  
October 21, 2009**

The President’s Council of Advisors for Science and Technology (PCAST) report uses a planning scenario where there could be a million Americans hospitalized and 150,000 to 300,000 needing intensive care. With the significant shortage of vaccine explored at the hearing we are likely in a position where there are a lot more people now in the intensive care units of the nation’s hospitals that we had hoped could have been prevented with that vaccine. Unfortunately, we know that the situation is becoming direr with every passing day. The FDA just announced that it was issuing an Emergency Use Authorization for intravenous (I.V.) antiviral medications that will help to save lives when traditional pill based antivirals are not enough.

**Question: How many people are currently projected to be in hospital ICUs as a result of H1N1 or resultant viral secondary infections? What projections is CDC considering for the levels in the coming weeks?**

**Answer:** Monitoring for rapid increases in rates of disease (influenza-like illness), hospitalizations, and deaths is critical to maintaining health care system situational awareness. CDC conducts surveillance for disease, hospitalizations, and deaths through a variety of national systems and produces a weekly report that is available at <http://www.cdc.gov/flu/weekly/>. From August 2009 through January 2, 2010, 20 percent of people admitted to the hospital with a laboratory test demonstrating influenza were admitted to the ICU during their hospital stay. This estimate is made from surveillance through the Emerging Infections Program sites in 10 states.

The Aggregate Hospitalization and Death Reporting Activity (AHDRA) system was implemented on August 30, 2009, and replaces the weekly report of laboratory confirmed 2009 H1N1-related hospitalizations and deaths that began in April 2009. Jurisdictions can now report to CDC counts of hospitalizations and deaths resulting from all types or subtypes of influenza, not just those from 2009 H1N1 influenza virus. To allow jurisdictions to implement the new case definition, counts were reset to zero on August 30, 2009. From August 30, 2009 – January 2, 2010, 37,778 laboratory-confirmed influenza-associated hospitalizations and 1,735 laboratory-confirmed influenza-associated deaths were reported to CDC. CDC will continue to use its traditional surveillance systems to track the progress of the 2009-10 influenza season.

Currently the number of individuals requiring hospitalization are decreasing in most parts of the country.

**Question:** How many people might benefit from an I.V. antiviral medication?

**Answer:** In response to the current 2009 H1N1 influenza outbreak and now pandemic, this is the first time that an IV antiviral has been used to treat influenza under an emergency use authorization (EUA). Patients hospitalized with 2009 H1N1 influenza are recommended to be treated with antiviral medications. A small number of very ill patients who are not able to take the medications that are currently available in a pill, liquid, or inhaled form may benefit from intravenous antiviral medications. Because there are no Food and Drug Administration (FDA)-approved antiviral medications that can be administered intravenously to treat influenza, the FDA issued an emergency use authorization on Oct. 23 to allow use of intravenous peramivir, an investigational antiviral drug in the class of drugs known as neuraminidase inhibitors.

The emergency use authorization for IV peramivir allows doctors to prescribe the drug to treat certain adults and children hospitalized with confirmed or suspected 2009 H1N1 infections. Specifically, IV peramivir is authorized only for hospitalized adult and pediatric patients for whom therapy with an IV drug is clinically appropriate.

To help meet the potential need for IV medications that may be useful in treating the H1N1 virus, HHS procured and placed into the Strategic National Stockpile (SNS) 1,200 5-day courses of IV peramivir on October 23, 2009, and on November 5, 2009, announced that it has procured an additional 10,000 5-day treatment courses. Clinicians may prescribe Peramivir IV for a 5 to 10 day course of therapy. Through January 7, 2010, CDC has provided product for a total of 1,105 requests for IV peramivir, including 98 pediatric requests. To support these requests, a total of 1,723 5-day peramivir regimens have been deployed from the SNS.

**Question: Do you expect HHS to acquire I.V. antiviral medications? If so how many doses and how soon?**

**Answer:** In October 2009, the U.S. Department of Health and Human Services (HHS) awarded three contracts for up to 120,000 treatment courses of intravenous (IV) antiviral drugs to help treat hospitalized 2009 H1N1 influenza patients. The HHS Food and Drug Administration (FDA) issued an emergency use authorization on October 23 to allow use of the intravenous drug Peramivir IV to treat certain hospitalized flu patients. In addition to 1,200 treatment courses obtained through existing Biomedical Advanced Research and Development Authority (BARDA) advanced development contracts, 10,000 treatment courses of Peramivir IV have been purchased by BARDA and provided by the manufacturer for distribution by HHS' Centers for Disease Control and Prevention (CDC). The contracts allow HHS to purchase more Peramivir IV, as well as contracts with two other manufacturers for other IV antiviral drugs, if they are also granted use under Emergency Use Authorization by the FDA and as events dictate.

**Question:** How will any acquired I.V. antivirals be deployed?

**Answer:** A licensed clinician treating a patient may request intravenous peramivir under the emergency use authorization (EUA) only from CDC. Clinicians can place orders through an electronic system at <http://emergency.cdc.gov/h1n1antivirals/2.asp> or by calling CDC. CDC distributes the drug directly to a hospital pharmacy designated by the clinician, as outlined in the Emergency Use Authorization for peramivir. After the request is received and a decision has been made to ship to a receiving hospital, CDC's Strategic National Stockpile (SNS) delivers the peramivir directly to the hospital. Once in its possession, the receiving hospital must maintain adequate records for the receipt, use, and disposition of the peramivir.

**Post-Hearing Questions for the Record  
Submitted to the Honorable Kathleen Sebelius  
From Senator Daniel K. Akaka**

**“H1N1 Flu: Monitoring the Nation’s Response”  
October 21, 2009**

**Question:** I have long been concerned with the potential effects of influenza on the federal workforce and government operations. Could you describe how the Department is tracking the spread of H1N1 flu within its workforce, what resources or services are being provided to infected workers, and what information is provided to other employees who may have been exposed to H1N1?

**Answer:** Surveillance and monitoring of the federal workforce for illness is the responsibility of each individual agency. The Department does not track the spread of 2009 H1N1 influenza within our workforce, as tracking employees and identifying their illness is a violation of an employee’s privacy.

During the summer of 2009, the Federal Advisory Council on Occupational Safety and Health (FACOSH) Emerging Issues Workgroup met to analyze the federal agency experience during the spring 2009 H1N1 influenza outbreak. FACOSH advises the Secretary of Labor on issues related to the occupational safety and health of the federal workforce. CDC, including National Institute of Occupational Safety and Health (NIOSH) representatives, participated in the workgroup activities as technical advisors. The workgroup gathered information from federal agencies and labor organizations representing federal employees. It also sought insight from technical experts who provided perspective on the occupational safety and health-related gaps that exist in pandemic planning within the federal government and provided recommendations for the Secretary of Labor, including providing better all-around pandemic-related training within federal agencies and facilitating the coordination of H1N1 influenza information to improve consistency and clarity.

CDC has developed guidance that recommends actions that non-healthcare employers should take now to decrease the spread of seasonal flu and 2009 H1N1 flu in the workplace and to help maintain business continuity during the 2009–2010 flu season (located at <http://www.cdc.gov/h1n1flu/business/guidance/>). The Department of Labor’s Occupational Safety and Health Administration (OSHA) has developed H1N1 guidance for healthcare workers and employers, as well as for non-healthcare workers and non-healthcare employers. OSHA has also issued a directive on enforcement procedures for high to very high occupational exposure risk to 2009 H1N1 influenza. These OSHA documents are located at <http://www.osha.gov/h1n1/>.

In addition, CDC offers evaluation and treatment to those thought to have had occupational exposures. In general the CDC Occupational Health Clinic contract does

not cover evaluation and treatment of non-occupational illnesses/injuries other than first aid and similar services.

The Department ensures that basic infection control and symptom vigilance information is widely available, and more detailed information and links to CDC and HHS Influenza websites are provided to individual workers and workgroups upon request or when indicated when CDC's Office of Health and Safety becomes aware of a potential workplace exposure.

**Post-Hearing Questions for the Record  
Submitted to the Honorable Kathleen Sebelius  
From Senator Thomas R. Carper**

**“H1N1 Flu: Monitoring the Nation’s Response”  
October 21, 2009**

I have had brought to my attention a software that models disease spread developed through the Office of Naval Research. This software was used successfully by ONR and HHS in evaluating the effectiveness of various responses to the spring 2009 H1N1 flu outbreak in Mexico and the Southern Hemisphere, including supporting decisions made by US Northern Command and HHS such as whether to close the US Mexico border.

As a former governor, I can see the usefulness of this software for mayors and governors, whose public health staff must develop the appropriate responses to the H1N1 flu that is breaking out across the US.

As the cabinet agencies on the front lines of responding to the current outbreak, are you aware of this technology developed through ONR? **If so, has the federal government given thought to making it available to cities and states to enable them to develop the most appropriate response to the outbreaks?**

**Answer:** HHS reviewed a variety of disease spread models, including the ONR software; however, we did not request models for discussions about border closings because H1N1 influenza was already present within the United States and border closings would not have helped efforts to control the disease. CDC has a suite of software tools explicitly designed to help state, local and federal governments, as well as hospitals and businesses, plan and prepare responses to influenza pandemics. There have been more than 100,000 downloads of the software suite during the past eight years. These programs have been downloaded recently at a rate of about 500 per week. Special editions of these models are being prepared, with data from the 2009 H1N1 influenza pandemic as the default values. These resources soon will be available with revised information based on patterns of influenza disease seen in spring 2009.

HHS/CDC pandemic planning tools have been used extensively by at least 20 national governments. For example, HHS/CDC recently sent the Mexico's Ministry of Health advance copies of our software updated with values for 2009 H1N1 influenza. The Ministry translated those into Spanish and distributed them to their local public health units. Also, at the request of Pan American Health Organization (PAHO), HHS/CDC has conducted several training classes for PAHO member states on the use of these software tools. Most ministries of health in PAHO member states have used them to help plan and prepare for influenza pandemics. The World Health Organization (WHO) has translated copies into Vietnamese, and those translations

are available on the WHO website. The following describes influenza pandemic planning software tools developed by HHS/CDC that currently are available for downloading from the CDC web site:

- **CommunityFlu** is a software program that simulates the spread of influenza through a model community, and the impact of a variety of potential interventions (e.g., vaccinations, school closings, wearing of face masks, patient and household isolation/self quarantine). CommunityFlu also calculates the cost, in terms of workdays lost, of influenza and the associated interventions. <http://www.cdc.gov/flu/tools/communityflu/>
- **FluLabSurge** is a spreadsheet-based program designed to assist laboratory directors forecast demand for specimen testing during an influenza pandemic (i.e., the surge in demand), and develop response plans. <http://www.cdc.gov/flu/tools/flulabsurge/>
- **Flu Surge** is a spreadsheet-based model which provides hospital administrators and public health officials estimates of the surge in demand for hospital-based services during an influenza pandemic. FluSurge estimates the number of hospitalizations and deaths of an influenza pandemic (whose length and virulence are determined by the user) and compares the number of persons hospitalized, the number of persons requiring ICU care, and the number of persons requiring ventilator support during a pandemic with existing hospital capacity. <http://www.cdc.gov/flu/tools/flusurge/>
- **FluAid** is designed to assist state and local level planners in preparing for an influenza pandemic by providing estimates of potential impact specific to their locality. FluAid provides only a range of estimates of impact in terms of deaths, hospitalizations, and outpatients visits due to pandemic influenza. <http://www.cdc.gov/flu/tools/fluaid/>
- **FluWorkLoss** estimates the potential number of days lost from work due to an influenza pandemic. Users can change almost any input value, such as the number of workdays assumed lost when a worker becomes ill or the number of workdays lost due to a worker staying home to care for a family member. Users can also change the length and virulence of the pandemic so that a range of possible impacts can be estimated. FluWorkLoss provides a range of estimates of total workdays lost, as well as graphic illustrations of the workdays lost by week and percentage of total workdays lost to influenza-related illnesses. <http://www.cdc.gov/flu/tools/fluworkloss/index.htm>

**Question:** As we face a nationwide H1N1 outbreak, does the federal government currently have technology that allows policymakers to accurately predict the effectiveness of different measures – such as closing schools, wearing facemasks, etc.?

**Answer:**

**Vaccine effectiveness:** CDC is examining the effectiveness of seasonal and pandemic influenza vaccines in preventing different influenza-associated outcomes such as illness or hospitalizations. The findings of these studies are then used to inform vaccination policy.

In 2004, a 3-year CDC-funded pilot study with the Marshfield Clinic Research Foundation was initiated to develop an assessment system of the vaccine's effectiveness across all groups for whom influenza vaccine is targeted. In 2008, CDC expanded this pilot study to include 3 additional sites (University of Michigan, University of Rochester, and Vanderbilt University). Studies conducted by these four sites will evaluate the effectiveness of both seasonal and 2009 H1N1 influenza vaccines.

Through CDC's Emerging Infections Program Network, the effectiveness of the pandemic vaccine in preventing laboratory-confirmed influenza hospitalizations will be assessed in people of all ages. In addition, the effectiveness of seasonal influenza vaccine will be studied among those aged 50 years and older in the second year of a planned 3-year study.

**Antiviral resistance:** Influenza viruses constantly change as the virus makes copies of itself (i.e. replicates). The ability to constantly change is a hallmark of influenza viruses. Flu viruses often change from one season to the next or they can even change within the course of one flu season. Some changes can result in the viruses being resistant to one or more of the antiviral drugs that are used to treat or prevent influenza.

Samples of viruses collected from around the United States and worldwide are studied to determine if they are resistant to any of the four FDA-approved influenza antiviral drugs. CDC routinely collects viruses through a domestic and global surveillance system to monitor for changes in influenza viruses.

The vast majority of 2009 H1N1 viruses examined to date are susceptible to the neuraminidase inhibitor antiviral medication oseltamivir; however, rare sporadic cases of oseltamivir resistant 2009 H1N1 viruses have been detected worldwide. All tested viruses are susceptible to the neuraminidase inhibitor zanamivir. Occasional development of oseltamivir resistance during treatment or prophylaxis is not unexpected.

To prevent the spread of antiviral resistant virus strains, CDC reminds clinicians and the public of the need to continue hand and cough hygiene measures for the duration of any symptoms of influenza, even while taking antiviral medications (<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5832a3.htm>). CDC will continue ongoing surveillance and testing of influenza viruses. Additionally, CDC is working with the state public health departments and the World Health Organization to collect additional information on oseltamivir resistance in the U.S. and worldwide.

**School Closures:** Our knowledge of the effectiveness of school closures on slowing the spread of influenza disease among children and adults in that school as well as in the community at large is based on several types of data. CDC is currently conducting epidemiologic field investigations that explore the spread of influenza among school children who attended schools that were closed (usually only 1-2 days). CDC is also analyzing data from school closures that occurred last spring due to influenza. CDC also has compiled information from both domestic and international investigations where schools closed during the spring bout of this pandemic to try to better understand the impact of school closures on influenza transmission.

**Technology Models:** In regard to technology, CDC has developed several interactive models that are now available on the Internet. These models provide estimates for planning purposes and are refined and updated on an ongoing basis. Examples of these models include:

- **CommunityFlu:** simulates the spread of influenza through a model community, and the impact of a variety of potential interventions (e.g., vaccinations, school closings, wearing of face masks, patient and household isolation/self quarantine). CommunityFlu also calculates the cost, in terms of workdays lost, of influenza and the associated interventions. <http://www.cdc.gov/flu/tools/communityflu/>
- **FluSurge:** a spreadsheet-based model which provides hospital administrators and public health officials estimates of the surge in demand for hospital-based services during the next influenza pandemic. FluSurge estimates and compares the number of persons hospitalized, the number of persons requiring ICU care, and the number of persons requiring ventilator support during a pandemic with existing hospital capacity. <http://www.cdc.gov/flu/tools/flusurge/>
- **FluAid:** provides estimates of potential impact specific to a locality, to assist state and local level planners in preparing for the next influenza pandemic. FluAid provides only a range of estimates of impact in terms of deaths, hospitalizations, and outpatients visits due to pandemic influenza. <http://www.cdc.gov/flu/tools/fluaid/>
- **FluWorkLoss:** estimates the potential number of days lost from work due to an influenza pandemic. Users can change almost any input value, such as the number of workdays assumed lost when a worker becomes ill or the number of workdays lost due to a worker staying home to care for a family member. Users can also change the length and virulence of the pandemic so that a range of possible impacts can be estimated. <http://www.cdc.gov/flu/tools/fluworkloss/index.htm>

Further, CDC is in constant dialogue with State, local, and North American public health agencies, as well as those from other countries around the world and WHO, to share ideas and learn about and make available other tools and strategies developed elsewhere.

**Question:** I wanted to follow up on Chairman Lieberman's request that the "over order" of IV antivirals. What is the right number of courses we need to ensure that

doctors across the country have immediate accessibility to these IV antivirals that can help save the lives of some of our most critical patients suffering from H1N1?

**Answer:**

Peramivir, the intravenous formulation of antiviral product authorized for use under the FDA-issued Emergency Use Authorization (EUA), is currently available for clinicians to order and is being used to treat patients.

Only a licensed clinician treating a patient may request intravenous peramivir under the EUA from CDC. Clinicians can place orders through a web portal at <http://emergency.cdc.gov/h1n1antivirals/2.asp> or by calling CDC. CDC distributes the drug directly to a location within a hospital designated by the clinician, as outlined in the drug's emergency use agreement. CDC endeavors to deliver the peramivir within 24 hours of receiving and confirming a valid request. To date, nearly all doses have been delivered within 24 hours. We believe that this will allow for rapid access of this resource.

In October 2009, the U.S. Department of Health and Human Services (HHS) awarded three contracts for up to 120,000 treatment courses of intravenous (IV) antiviral drugs to help treat hospitalized 2009 H1N1 influenza patients. The HHS Food and Drug Administration (FDA) issued an emergency use authorization on October 23 to allow use of the intravenous drug Peramivir IV to treat certain hospitalized flu patients. In addition to 1,200 treatment courses obtained through existing Biomedical Advanced Research and Development Authority (BARDA) advanced development contracts, 10,000 treatment courses of Peramivir IV have been purchased by BARDA and provided by the manufacturer for distribution by HHS' Centers for Disease Control and Prevention (CDC).

**Post-Hearing Questions for the Record  
Submitted to the Honorable Kathleen Sebelius  
From Senator Roland W. Burris**

**“H1N1 Flu: Monitoring the Nation’s Response”  
October 21, 2009**

**Question:** I listened with great interest as Chairman Lieberman discussed the need for intravenous antivirals and appreciated your statement that an Emergency Use Authorization was coming within days. To follow up, because doctors have stated that critical patients deteriorate quickly - what plans are in place to ensure that these intravenous antivirals are accessible to doctors immediately in hospital pharmacies?

**Answer:**

Peramivir, the intravenous formulation of antiviral product authorized for use under the FDA-issued Emergency Use Authorization (EUA), is currently available for clinicians to order and is being used to treat patients.

A licensed clinician treating a patient may request intravenous peramivir only from CDC. Clinicians can place orders through a web portal at <http://emergency.cdc.gov/h1n1antivirals/2.asp> or by calling CDC. CDC distributes the drug directly to a location within a hospital designated by the clinician, as outlined in the drug’s emergency use agreement. CDC endeavors to ship the peramivir within 24 hours of receiving and accepting the request. We believe that this will allow for immediate, equitable access of this critical resource.

In October 2009, the U.S. Department of Health and Human Services (HHS) awarded three contracts for up to 120,000 treatment courses of intravenous (IV) antiviral drugs to help treat hospitalized 2009 H1N1 influenza patients. The HHS Food and Drug Administration (FDA) issued an emergency use authorization on October 23 to allow use of the intravenous drug Peramivir IV to treat certain hospitalized flu patients. In addition to 1,200 treatment courses obtained through existing Biomedical Advanced Research and Development Authority (BARDA) advanced development contracts, 10,000 treatment courses of Peramivir IV have been purchased by BARDA and provided by the manufacturer for distribution by HHS’ Centers for Disease Control and Prevention (CDC). The contracts allow HHS to purchase more Peramivir IV, as well as contracts with two other manufacturers for other IV antiviral drugs, if they are also granted use under Emergency Use Authorization by the FDA and as events dictate.

**Post-Hearing Questions for the Record  
Submitted to the Honorable Kathleen Sebelius  
From Senator Susan M. Collins**

**“H1N1 Flu: Monitoring the Nation’s Response”  
October 21, 2009**

One of the failures our Committee found during our investigation of the response to Hurricane Katrina was the belief by many in the Federal Government that federal assistance for responding to a natural disaster could only be provided after a state had failed at its efforts to respond effectively. As we saw, such a policy had disastrous results, since this often meant that federal assistance arrived much too late. As we prepare for an H1N1 pandemic, I remain concerned that your department is not taking a sufficiently proactive approach to anticipating where gaps might be at the state and local levels and addressing those gaps early.

For example, some experts are concerned that HHS is leaving states to their own devices in terms of vaccinating their populations. While HHS has issued guidance for setting up immunization clinics, it has not provided technical assistance with actually setting up these clinics. HHS should be working closely with state public health and emergency management offices to provide hands-on federal assistance now, rather than waiting for states or localities to falter.

**What specific steps is your department taking to provide this much needed assistance proactively to those who need it?**

**Answer:** HHS/ASPR has created and trained 15 vaccination teams consisting of a nurse/pharmacist, four paramedics and three emergency medical technicians to assist states in the vaccination of their residents. These teams are from the National Disaster Medical System (NDMS). A vaccination team has an approximate throughput of 400 vaccinations per day.

In response to a request from the State of Delaware, support was provided in two phases; the first phase starting on November 20, 2009 and ending on November 22, 2009, the second phase starting on December 15, 2009 and ending on December 17, 2009.

Two additional deployments are planned in response to requests from the US Virgin Islands and American Samoa, both for school based vaccinations. One team will deploy to American Samoa to conduct vaccination clinics from January 17 – 31, 2010. Two teams will deploy to the US Virgin Islands to conduct vaccination clinics from January 11 – 22, 2010.

HHS has Regional Emergency Coordinators (RECs) in each of the 10 HHS regions to assist in response efforts and to collaborate with states/tribes/territories to develop plans and conduct exercises. During the H1N1 pandemic, the RECs have offered technical advice to every state and have served as a major conduit between HHS and the state health departments. The RECs continue to work with the states to answer questions about use of federal resources, clarify federal guidance and identify gaps in the response. RECs report to ASPR through twice weekly ESF-8 calls, which are attended by the HHS regional offices, HHS Operations Divisions (CDC, FDA, CMS), and the federal interagency ESF-8 partners.

To ensure that HHS can be proactive in anticipating when states are in need of assistance HHS/ASPR leads the HavBed surveillance effort. Since its inception in 2002, ASPR's Hospital Preparedness Program (HPP) has provided more than \$3 billion to fund the development of medical surge capacity and capability at the State and local level. HPP has required recipients to implement a system of bed counting, called the "Hospital Available Beds in Emergencies and Disasters" (HAVBED), which requires reports of available beds, including a count of available adult and pediatric general beds and ICU beds, to State and HHS emergency operations centers within four hours of request. Since October 2009, HAVBED has been operational and collecting information from States about hospital status and has enhanced our 2009 H1N1 medical surge response. Based on the lessons learned from the spring 2009 H1N1 response, HAVBED was modified to also collect information about hospital stress.

ASPR is also working with CDC to monitor influenza-associated burden on intensive care units (ICUs), using a tool that complements the HAVBED system. Making use of two academic ICU networks (one adult and one pediatric), CDC is gathering weekly data that assess the impact that the influenza outbreak is having on ICUs in terms of personnel and other hospital resources currently being used to care for influenza patients. These weekly "snapshots" of pandemic influenza stresses to the ICU system will provide information that will both aid proactive planning, as well as ensure a timely HHS response.

In order to hasten the development of effective therapy for Acute Respiratory Distress Syndrome (ARDS), the National Heart, Lung, and Blood Institute, at HHS's National Institutes of Health, initiated a clinical network to carry out multi center clinical trials of ARDS treatments. For 2009 H1N1, ASPR and CDC have partnered with NHLBI and the ARDSNet to establish an adult registry of critically ill patients from novel influenza.

Representatives from the U.S. Food and Drug Administration are also involved with the registry. The goal of the registry is to obtain a better understanding of the burden of disease, severity of illness, clinical course, and resource utilization needed to optimize patient care for 2009 H1N1 associated critical illness. The ARDSNet dataset will collect data from more than 50 ICUs from 42 hospitals in the Network. The Pediatric Acute Lung Injury and Sepsis Investigator's (PALISI) Network joined this

novel partnership and are leading the registry efforts regarding the pediatric experience with H1N1 associated critical illness.

The ARDSNet and PALISI registry is being funded by NHLBI and will contain information on up to 2,250 individuals admitted to the ICU with confirmed or suspected influenza, both 2009 H1N1 and seasonal influenza. Most patients will be collected prospectively; however, a subset of patients will be accrued retrospectively. Institutional Review Boards must approve the registry procedures for all sites. ARDSNet and PALISI have developed a protocol for collection and rapid analysis of data on 2009 H1N1 patients to ensure early learning that can inform clinicians.

The Office of the Assistant Secretary for Preparedness and Response and the ARDS Network Clinical Coordinating Center will rapidly analyze data for near-real time reporting to inform government response policy as well as timely reporting to front-line clinicians to impact clinical care.

Following Congressional appropriation of funding for response to ongoing and emerging outbreaks of 2009 H1N1 influenza in the United States, HHS/CDC has awarded to date \$1.35 billion through the Public Health Emergency Response (PHER) grant for state and local pandemic influenza preparedness and response, including H1N1 vaccination. Funding has been awarded in three phases to 62 awardees, including:

- o 50 states
- o 8 territories and freely associated states
- o 4 localities (Chicago, Illinois; Los Angeles County, California; New York City, New York; and Washington, D.C.)

As a requirement of PHER Phase I and Phase II funding, the 62 PHER awardees conducted and submitted gap assessments to identify strengths and gaps in H1N1 pandemic influenza planning and response functions. HHS/CDC has analyzed the assessment data, and is using the results to better coordinate federal, state, and local H1N1 response strategies, as well as provide targeted technical assistance to awardees. For PHER Phase III, additional data collection and reporting will be conducted to update and monitor the status of awardee planning and response capacities and operational capabilities. On December 22, 2009, a Funding Opportunity Announcement for PHER Phase IV was made available for states to respond to which will provide additional funding for states to maintain their vaccination efforts through Spring 2010, with a special emphasis on reaching the priority populations set forth by the ACIP, populations with traditionally low vaccination rates, and utilizing retail sites for vaccine delivery. CDC expects awards will be made around February 15; however, as applications are received, they will be reviewed, so that we can release the funding more quickly if possible.

HHS' H1N1 state Coordination Task Force and Vaccine Task Force have been collaborating to identify and provide targeted technical assistance to enhance state and local H1N1 response. Following are highlights of activities that are underway.

- Weekly state and local coordination conference calls are held with state and local public health officials, vaccine planners, and partner organizations such as Association of state and Territorial Health Officials (ASTHO) and National Association of County and City Health Officials (NACCHO) to share up-to-date information and guidance from HHS/CDC and to address vaccine implementation and other H1N1 response issues that state and local partners raise. These calls supplement the ongoing consultation and technical assistance provided by HHS/CDC's immunization and Division of state and Local Readiness project officers who routinely work with state and local public health departments and provide ongoing technical assistance.
- Development and implementation of targeted technical assistance plans based on 2009 H1N1 gap assessments and follow-up conference calls with the 62 state and local Public Health Emergency Response (PHER) awardees to assess their readiness to implement vaccination campaigns and to identify gaps and other state and local technical assistance needs.
- Deployment of federal staff for short-term technical support of state and local mass vaccination campaigns. To date, approximately 149 individuals have been or will be deployed to jurisdictions that have requested assistance. Requests so far involve assistance with state call centers, helping to coordinate vaccination clinic operations, vaccine ordering technical assistance, and assistance with epidemiologic and surveillance activities.
- Using PHER funds to hire direct assistance (DA) personnel, including epidemiologists, public health advisors, and medical officers, who are assigned to PHER awardees to augment their public health workforce.
- Collecting and disseminating state and local "useful lessons" from the field to facilitate more effective mass vaccination campaigns across the country.

Below are a few examples of targeted technical assistance CDC has provided to improve vaccine ordering and distribution.

- One awardee had challenges preventing its 2009 H1N1 vaccines from freezing. Based on technical assistance provided by HHS/CDC's vaccine team through multiple episodes of support and information exchanges, the awardee modified its storage practices, invested in additional specialized tools/refrigerators/gel packs, and other supplies to maintain the proper cold chain storage procedures and have not reported any additional frozen vaccines since HHS/CDC provided the awardee with technical assistance.
- Another awardee had challenges and potential delays in ordering nasal spray flu vaccine or LAIV (live attenuated influenza vaccine), as the awardee thought it also had to order ancillary vaccine supply kits, thus delaying the

ordering process. After HHS/CDC provided one-on-one technical assistance, the awardee was educated on the proper ordering procedures for LAIV, thus preventing further delays in its vaccine ordering procedures.

- HHS/CDC is assisting individual state and territorial public health departments with implementing a web-based 2009 H1N1 flu vaccine locator at public sites. HHS, in partnership with the American Lung Association and Google, is building the web-based locator tool. The locator will be prominently displayed on [www.flu.gov](http://www.flu.gov) and on Google when a search is conducted for flu information. The locator will also be available on state and territorial health department websites. Members of the public will be able to enter their zip code and access a map showing vaccination locations with addresses, hours of operation, and driving directions. HHS/CDC is supporting the locator's implementation and is coordinating these efforts by leveraging existing vaccine tracking information, supporting the installation of the web-based tool, and publishing the data to the health departments' websites with linkages to [www.flu.gov](http://www.flu.gov).
1. Last month, the Inspector General of HHS released two reports critical of various states' planning and preparedness efforts for 2009 H1N1. However, the information that informed the IG's analysis was somewhat outdated, as the IG was using data collected in the summer of 2008. Still, the IG released a series of recommendations for how HHS could better work with states to improve their preparedness for a pandemic.

These recommendations included better coordination with states to improve surge efforts, ensuring that states and localities better document lessons learned from exercises, and providing more training and technical assistance to states.

**What has HHS done to act upon these recommendations?**

**Answer:** The Assistant Secretary for Preparedness and Response's (ASPR) Hospital Preparedness Program, which provides grant investments to state/territory departments of public health to improve surge capacity and enhance community and hospital preparedness for public health emergencies, has restructured progress reporting to better capture healthcare system lessons learned from exercises, and have increased the program's ability to provide more healthcare system specific grant related technical assistance to states. Also, ASPR and the DHS Office of Health Affairs created a new grant steering committee to improve coordination among HHS and DHS grant programs.

The Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) is a program for states to develop rosters of personnel who can provide health services during a public health emergency. All 50 states are establishing ESAR-VHP programs. Currently, 49 states and the District of Columbia have

operational ESAR-VHP systems. There are over 147,600 registered ESAR-VHP volunteers. The ASPR ESAR-VHP program is providing intensive technical assistance to the states, including volunteer recruitment assistance and access to national data sources for credentials verification. In FY 2009, ESAR-VHP started a new small grants program to increase the capacity and ensure the sustainability of the existing state and Territorial ESAR-VHP programs. Fifty-three (53) applications were received and approved for funding.

HHS worked closely with state and local public health authorities in the spring and summer of 2009 to enhance their capacity to distribute and administer vaccine and other medical supplies to their jurisdictions. CDC continues to provide technical assistance to its grantees as state and local public health departments administer their vaccine campaigns, and regularly shares promising practices between health departments to promote good vaccine implementation activities.

**Post-Hearing Questions for the Record  
Submitted to the Honorable Kathleen Sebelius  
From Senator John McCain**

**“H1N1 Flu: Monitoring the Nation’s Response”  
October 21, 2009**

**What is the projected date when you believe all states will receive their requested number of H1N1 vaccines?**

**Answer:** HHS has said from the start that flu is unpredictable, and so is the production of flu vaccine. Initial vaccine production took longer than manufacturers expected because of the time it takes to grow the antigen for the vaccine. As of January 11, 2010, 147,692,700 H1N1 vaccine doses have been allocated to the states. States are continuing to order approximately 82 percent of the vaccine doses available to them. While vaccine supply had a slow start, it’s actually a significant achievement to have, this quickly, what we believe is a safe and very effective vaccine to fight a pandemic flu. More vaccine continues to come on line every day.

**Post-Hearing Questions for the Record  
Submitted to the Honorable Kathleen Sebelius  
From Senator Lindsey Graham**

**“H1N1 Flu: Monitoring the Nation’s Response”  
October 21, 2009**

While we work to prepare a pandemic strain vaccine for H1N1, we are reliant on antivirals to prevent and treat influenza before it is ready or available in sufficient quantities needed for mass distribution.

I understand the National Strategy on Pandemic Influenza relies on states purchasing 31 million courses of treatment, but to date, it’s my understanding that only 25.5 million courses of treatment have been purchased.

At this point, some of the states affected by H1N1 earlier this year received disbursements from the Strategic National Stockpile – some of which they have already been distributed. Some states have purchased all of their allocations and still have them on hand, and several states have purchased far less of the medications than are needed to protect 25 percent of their population even with federal help, which is the benchmark set by the National Strategy on Pandemic Influenza.

**Does HHS plan to address this shortfall in state stockpiling efforts?**

**Answer:** At this time, we do not have any plans to increase the percentage of the population that we would seek to cover with antivirals. In the spring, approximately 11 million treatment courses of antiviral drugs were deployed from the Strategic National Stockpile (SNS) to the 62 project areas, and an additional 536,000 courses of Tamiflu® oral suspension were released for pediatric usage in the fall. There was only modest use of this product at the state level. Thirteen million regimens of antiviral drugs were purchased to replenish these assets and were incorporated into SNS inventory over the summer. HHS has also made an additional purchase of 16 million treatment courses of antiviral drugs that are anticipated to be delivered through February 2010. HHS believes that these additional purchases offset the gap that was originally present in state stockpiles (5.5 million treatment courses) in April 2009.

**Will any of the \$7.5 billion included in the FY09 supplemental for pandemic influenza preparation be used to help states that have lagged behind to make up the gap in terms of the antivirals they should have on hand?**

**Answer:** States received 11 million treatment courses in May 2009 from the SNS to add to their state stockpiles (collectively 25.5 million treatment courses). An additional 536,000 treatment courses of antiviral oral suspensions for pediatric populations was recently deployed to states from the SNS. The SNS has been

replenished above the 50 million treatment course level, and antivirals can be deployed again to states from the SNS as warranted. Additionally states purchased another 2 million courses of antivirals since May 2008 for their own stockpiles. Lastly, HHS will continue to assist states with federal subsidies to procure influenza antivirals drugs using “best-price” federal contracts.

1. The National Strategy on Pandemic Influenza (NSPI) generally relies on the development of a vaccine to protect our public. At the same time, I am sensitive to the fact that antivirals also play an important role in the National Strategy in the time before a vaccine is available during a pandemic strain of influenza.

Despite your good and sincere efforts at public education to date, we have seen some doubts about vaccination that leaves me concerned and I am sure concerns my colleagues as well. When I see a court in New York step in to stop vaccination requirements for health care workers, nurses who may be exposed to H1N1 on a daily basis, I have to ask **what our Plan B might be for taking care of people if they won't agree to be vaccinated?**

**Answer:** We believe that every American, particularly individuals in the high-risk target groups, should have the opportunity to be vaccinated against H1N1. Vaccinations are a proven public health intervention that saves lives. We recognize, however, that a segment of the population will not get vaccinated. Many people who are hesitant about vaccination can be influenced by effective information and risk communication regarding the benefits and risks of vaccine compared with the disease. However, no health intervention is expected to be adopted by all individuals. For these individuals, as well as Americans in general, we continue to urge the following everyday steps to protect their health:

- Cover your nose and mouth with a tissue when you cough or sneeze. Throw the tissue in the trash after you use it.
- Wash your hands often with soap and water. If soap and water are not available, use an alcohol-based hand rub.
- Avoid touching your eyes, nose or mouth. Germs spread this way.
- Try to avoid close contact with sick people.
- If you are sick with flu-like illness, CDC recommends that you stay home for at least 24 hours after your fever is gone except to get medical care or for other necessities. (Your fever should be gone without the use of a fever-reducing medicine.) Keep away from others as much as possible to keep from making others sick.
- If you are sick with flu-like illness and you have either severe symptoms or fall into a risk group (e.g., pregnancy, chronic medical conditions, age under 2 years or over 65 years), prompt treatment with antiviral medications may be very important and you should consult with a health care provider.

**Other important actions that individuals can take include:**

- Follow public health advice regarding school closures, avoiding crowds and other social distancing measures.
- Be prepared in case you get sick and need to stay home for a week or so; a supply of over-the-counter medicines, alcohol-based hand rubs (for when soap and water are not available), tissues and other related items could help you to avoid the need to make trips out in public while you are sick and contagious.

Regarding healthcare workers who are skeptical about influenza vaccination, HHS/CDC continues to work with healthcare provider and clinician organizations to emphasize the evidence supporting the safety of this vaccine (and the seasonal influenza vaccine) while continuing to actively monitor the performance (degree of safety and effectiveness) of the current vaccine among those who receive it and continuing to strongly encourage healthcare workers to avail themselves of the vaccine. We are carrying out substantial outreach efforts using health promotion, new and traditional media channels and trusted partners to assure accurate messages about H1N1 vaccines reach the target populations. In addition, it remains important to reiterate that the best protection comes from following all of the recommended infection control precautions, as outlined in current HHS/CDC guidance ([http://www.cdc.gov/h1n1flu/guidelines\\_infection\\_control.htm](http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm)).

**Now, we have set a 25 percent benchmark for our antiviral stockpiling efforts for treatment of Americans in the event of a pandemic while other countries are stockpiling at much higher ratios – for example, both France and Great Britain are stockpiling enough antivirals for 50 percent of the population. What is the basis on which the federal government justifies the 25 percent benchmark for stockpiling antivirals for treatment that has guided our policy to date?**

**Answer:** The Federal Government established two primary goals for stockpiling existing antiviral medications in the 2007 National Strategy for Pandemic Influenza: (1) the establishment and maintenance of stockpiles adequate to treat 75 million persons, divided between federal (44 million regimen goal) and state stockpiles (31 million regimen goal) and (2) the establishment and maintenance of a federal stockpile of 6 million treatment courses reserved for containment efforts. In 2008, HHS promulgated updated guidance on antiviral use during an influenza pandemic. This updated guidance was a result of expanded antiviral production that supported an expansion beyond treatment to preventative use of antiviral drugs.

As a result of the updated guidance ([http://www.flu.gov/individualfamily/vaccination/antiviral\\_use.pdf](http://www.flu.gov/individualfamily/vaccination/antiviral_use.pdf)), our treatment goal shifted to shared federal and state stockpiles of 79 million regimens. Key parameters for this estimation include the attack rate of pandemic disease, the proportion of persons with pandemic illness who are treated, the responsiveness of the pandemic virus to treatment and the potential need to adjust the dose or duration of treatment, and the ability to target treatment to persons with pandemic illness in the absence of a sensitive and specific point-of-care diagnostic test. In this guidance, HHS assumes an attack rate of 15 percent for pandemic illness in the context of

effective community mitigation and a positive predictive value of a clinical diagnosis of influenza-like illness (ILI) of 35 percent. We also assume 60 percent of persons with pandemic illness will be treated. Given these assumptions, for the first wave of a 1918-like pandemic, a total of about 79 million antiviral treatment courses would be needed to support a treatment strategy.

**Do you have any plans to increase the percentage of the population we would seek to cover, in terms of antiviral purchases? Why or why not? Even if you don't look to France or the U.K. for precedents, given the reluctance to be vaccinated here at home - whether rational or not - among apparently large groups of people, doesn't that suggest that we should increase our targets for stockpiling antivirals so we have the capacity to treat those who may become ill?**

**Answer:** At this time, we do not have any plans to increase the percentage of the population that we would seek to cover with antivirals. Antiviral treatment is focused upon treatment of all hospitalized patients with suspected or confirmed 2009 H1N1, and outpatients who have high-risk conditions, including young age, chronic medical conditions, immunosuppression, or pregnancy. In the spring of 2009, approximately 11 million treatment courses of antiviral drugs were deployed from the HHS Strategic National Stockpile to the 62 project areas, and an additional 536,000 courses of Tamiflu® oral suspension were released for pediatric usage in the fall. There was only modest use of this product at the state level. Thirteen million treatment courses of antiviral drugs were purchased to replenish these assets and have been incorporated into SNS inventory over the summer. HHS has also made an additional purchase of 16 million treatment courses of antiviral drugs that are anticipated to be delivered through February 2010. This will increase the number of doses available in the Federal and state stockpiles to over 107M treatment courses covering over a third of the U.S. population. Due to documented yet rare reports of resistance to oseltamivir (Tamiflu®) some of these additional purchases are to increase the availability of zanamivir (Relenza®) in the stockpile.

**Question:** As I am sure you are aware, antivirals can also be used for prophylaxis as well as treatment of influenza, including H1N1 influenza. In terms of a pandemic, I understand that both HHS and the Institute of Medicine have issued recommendations that call for additional antiviral stockpiling for health care workers and first responders because both would be such an important part of our national response to a pandemic influenza outbreak and would constantly be in contact with people who are ill. However, I also understand that you recently informed a group of Members of the House of Representatives who have sought to protect at-risk health care workers and first responders that HHS is not pursuing this approach given what it says are global demand and limited manufacturing capacity issues and the inability to stockpile these drugs in time for the re-emergence of the 2009 H1N1. While I realize there may not be the manufacturing capacity to deliver 109 million courses of treatment tomorrow, but it is my understanding that capacity has been growing since H1N1 emerged as a pandemic and that it would be possible to stockpile more

antivirals in the months ahead. Now, as I understand it, pandemics come in waves, and what we're facing now could re-emerge later as a greater threat, particularly if the strain mutates. Combine that with a reluctance to be vaccinated, and it seems to me that we may have a larger problem on our hands that we might have thought. I also understand that while H1N1 is understandably at the forefront of our concerns today, epidemiologists believe that other strains of influenza, like H5N1 and H3N2 also continue to keep public health experts up at night. If we had antivirals on hand – which work against multiple strains of the flu, unlike a vaccine – that might enhance our preparedness now and in the future.

**In that case, why aren't you more aggressively heeding HHS and IOM's own recommendations on antiviral stockpiling for prevention as well as treatment for health care workers and first responders?**

**Answer:** In the spring of 2009, approximately 11 million treatment courses of antiviral drugs were deployed from the HHS Strategic National Stockpile to the States, localities, and territories, and an additional 536,000 courses of Tamiflu® oral suspension were released for pediatric usage. There was only modest use of this product at the state level. This suggests that, moving forward, we focus on vaccination of health care workers and emergency medical personnel as the means of prophylaxis and use antivirals primarily for treatment. Nevertheless, thirteen million treatment courses of antiviral drugs were purchased to replenish these assets and have been incorporated into SNS inventory over the summer. HHS has also made an additional purchase of 16 million treatment courses of antiviral drugs that are anticipated to be delivered through February 2010. Due to documented yet rare reports of resistance to oseltamivir (Tamiflu®) some of these additional purchases are to increase the availability of zanamivir (Relenza®) in the stockpile. Presently, we believe this approach is appropriate. Future decisions to replenish antiviral drug supplies will be based upon determined need, policy and recommendations need for product, available manufacturer supply, and available funding.

**Question: Other than vaccination, what steps are you taking to protect health care workers and first responders in the event of a pandemic?**

**Answer:** CDC has recently issued updated interim guidance ([http://www.cdc.gov/h1n1flu/guidelines\\_infection\\_control.htm](http://www.cdc.gov/h1n1flu/guidelines_infection_control.htm)), as well as a companion set of questions and answers specifically directed toward healthcare workers ([http://www.cdc.gov/h1n1flu/guidelines\\_infection\\_control\\_qa.htm](http://www.cdc.gov/h1n1flu/guidelines_infection_control_qa.htm)). These guidance documents address the full panoply of recommended precautions for healthcare settings, including use of respirators and facemasks. All of these recommendations are based on the most current data and assessments and are continually re-evaluated and updated as conditions warrant. It should be noted that the information and recommendations in these documents are also applicable to first responders who are assisting individuals potentially infected with novel H1N1 influenza, but analogous guidance specifically directed toward first responders has also been issued ([http://www.cdc.gov/h1n1flu/guidance\\_ems.htm](http://www.cdc.gov/h1n1flu/guidance_ems.htm)).

CDC is actively communicating this guidance to these stakeholder groups. CDC has provided technical experts to a variety of standing teleconference calls with various stakeholder groups including labor unions representing healthcare workers and first responders, healthcare associations, infectious disease associations, and clinical care providers. CDC also continues to present in person at national conferences and meetings of these groups.

**Post-Hearing Questions for the Record  
Submitted to the Honorable Arne Duncan  
From Senator Daniel K. Akaka**

**“H1N1 Flu: Monitoring the Nation’s Response”  
October 21, 2009**

1. I have long been concerned with the potential effects of influenza on the federal workforce and government operations. Could you describe how the Department is tracking the spread of H1N1 flu within its workforce, what resources or services are being provided to infected workers, and what information is provided to other employees who may have been exposed to H1N1?

The Department is not currently tracking the spread of the 2009 H1N1 flu within its workforce; however, if the need arises, we can track those employees who self-report having the 2009 H1N1 flu. At present, there does not appear to be a widespread occurrence of the 2009 H1N1 flu among the general employee population. The Office of Personnel Management (OPM) has a mechanism in place to track absenteeism in the Federal workforce through Department and Agency payroll providers using leave codes already reported on a biweekly basis and to compare that data to the previous year’s data. The report does not specifically track the occurrence of H1N1 in Federal employees due to privacy concerns.

All Department employees have been encouraged to receive the seasonal flu shot, and individuals who are in the target groups, as identified by the Centers for Disease Control and Prevention (CDC), are encouraged to receive the 2009 H1N1 flu vaccine. Both vaccines are being offered free of charge to our employees. The Department has also posted information for the general Department population, in the form of Q&As on our intranet, along with information and web links to the Office of Personnel Management and the CDC. The Q&A information covers a wide range of issues related to the 2009 H1N1 flu, including possible exposure to the flu, use of leave, and teleworking. Employees have been reminded that they can use their sick leave and annual leave where appropriate to assist them in dealing with the 2009 H1N1 flu. In addition, we have issued a pandemic flu policy which will be activated should the need arise for further action.

**Post-Hearing Questions for the Record  
Submitted to the Honorable Arne Duncan  
From Senator Jon Tester**

**“H1N1 Flu: Monitoring the Nation’s Response”  
October 21, 2009**

1. During the hearing, you stated that you think education is underfunded, and one of the many places where education is underfunded is in the area of school nurses, and you agreed to check on that. You said we are “under-resourced in nurses -- urban, rural, and suburban.” I would like to know how much you considered elementary and secondary education districts to be underfunded.

**How many districts have been forced to cut their school nursing program?**

Analysis of data on the number of full-time equivalent nurses in our public schools in 1999-2000, 2003-2004, and 2007-2008 shows that our schools continue to be under-resourced in nurses, with an average of 0.7 nurses per school each year. Available data from the two more recent years show higher ratios of nurses to schools in urban (0.7) and suburban (0.8) schools than in rural schools, which have an average ratio of 0.6 per school. We do not have data to measure changes since 2007-08.

**How many schools have a full-time nurse in each of their schools?**

A 2007 National Association of School Nurses (NASN) study showed that 45 percent of public schools surveyed had a full-time nurse, 30 percent had a part-time nurse, and 25 percent are without a nurse.

**What is the average student to nurse ratio across the nation?**

Among schools that employ a nurse, the student-to-nurse ratio is 449:1 in elementary schools and 809:1 in secondary schools. NASN recommends a set of ratios that vary based on the population of the school. For example, NASN recommends a minimum 1:750 nurse-to-student ratio for healthy students, but only 14 states meet this recommended ratio. A national average is difficult to establish due to the wide variability of nurse-to-student ratios between states, but NASN estimates a national average ratio across all schools of 1:1,151. Ratios range from 1:750 in 14 states to 1:4,893 in Utah (Hawaii did not provide data). Montana ranks 48th among states, with 1 school nurse to 3,137 students (1:3,137).

Several states have adopted laws or policies that require a school nurse in every school or in certain schools. Delaware has a law requiring a school nurse in every school and Alabama has recently adopted a new law requiring school nurses in every school. South Carolina has a law requiring a school nurse in every elementary school.

**How does that proportion change from urban to rural and frontier school districts?**

There is wide disparity in urban and rural student-to-nurse ratios both between and within states. According to the National Center for Education Statistics, nurses who work in urban schools tend to serve more students than nurses in rural schools, but rural schools

are much less likely to have a nurse at all. For example, in 2007-08, for elementary schools, the average number of nurses per school was 0.72 in urban schools and 0.78 in suburban schools, compared to 0.65 in rural schools. In those elementary schools that have a licensed nurse, the nurse serves an average of 633 students in urban schools, 610 students in suburban schools, and 483 students in rural schools. In secondary schools, in 2007-08, the average number of nurses per school was 0.74 in urban schools, 0.84 in suburban schools, but only 0.65 in rural schools. Of those secondary schools with a licensed nurse, that person is serving 1,073 students in urban schools, 1,052 students in suburban schools, and 715 students in rural schools. Some 62 percent of secondary students in public schools are enrolled in secondary schools that average more than 1,000 students per nurse. An unpublished study conducted by NASN found that 50 percent of large city schools surveyed had a full-time Registered Nurse (RN), while only 30 percent of rural, non-metropolitan schools had a full-time RN.

**If you were to suggest standards for coverage, what student to school nurse ratio would you suggest?**

The Department of Education does not regulate nurse-to-student ratios. However, the CDC recommends a ratio of at least 1:750 in all schools. Further, NASN recommends a needs-based formula for determining full-time school nurse-to-student ratios. For example, NASN recommends ratios of:

- 1:750 well students;
- 1:225 for the student populations that may require daily professional school nursing services or interventions such as special education inclusions;
- 1:125 in student populations with special health care needs; and
- 1:1 in some cases for students with multiple disabilities.

**For those schools that have decided they can't afford to hire a school nurse, how do you suggest they prepare for, and manage, those students diagnosed with the H1N1 flu?**

First, the U.S. Department of Education recommends that the local educational agency (LEA) create a partnership with the local public health authority, which can help provide guidance and resources to the school community. We would encourage the LEA to also create partnerships with community health care providers, as appropriate, such as community health clinics or private providers.

We also recommend that the LEA develop or review its all-hazards plan, which should account for an infectious disease outbreak, and include considerations such as communications plans, as well as plans for mitigating the effects of, responding to, and recovering from the outbreak. The U.S. Department of Education offers extensive resources to assist schools with all-hazards planning efforts at <http://www.ed.gov/emergencyplan> and <http://rems.ed.gov>.

Under current conditions, the CDC in the Department of Health and Human Services offers the following guidance for schools:

- *Encourage students and staff to stay home when sick:*  
Those with flu-like illness should stay home for at least 24 hours after they no longer have a fever, or signs of a fever, without the use of fever-reducing medicines. They should stay home even if they are using antiviral drugs.
- *Separate ill students and staff (who become ill at school):*  
Students and staff who appear to have a flu-like illness should be sent to a room separate from others until they can be sent home. CDC recommends that they wear a surgical mask, if possible, and that those who care for ill students and staff wear protective gear, such as a mask.
- *Practice hand hygiene and respiratory etiquette:*  
The new recommendations emphasize the importance of the basic foundations of influenza prevention: stay home when sick, wash hands frequently with soap and water when possible, and cover nose and mouth with a tissue when coughing or sneezing (or a shirt sleeve or elbow if no tissue is available).
- *Undertake routine cleaning:*  
School staff should routinely clean areas that students and staff touch often with the cleaners they typically use. CDC does not believe any additional disinfection of environmental surfaces beyond the recommended routine cleaning is required.
- *Encourage early treatment of high-risk students and staff:*  
People at high risk for influenza complications who become ill with influenza-like illness should speak with their health care provider as soon as possible. Early treatment with antiviral medications is very important for people at high risk because it can prevent hospitalizations and deaths. People at high risk include those who are pregnant, have asthma or diabetes, have compromised immune systems, or have neuromuscular diseases.

For additional and more in-depth guidance for K-12 schools on responding to an H1N1 outbreak, please see CDC's guidance at: <http://www.cdc.gov/h1n1flu/schools/schoolguidance.htm>. Also, Federal guidelines are updated regularly on [www.flu.gov](http://www.flu.gov), the Federal repository for public information on H1N1.

**Statement of Chairman Joseph Lieberman**  
**Homeland Security and Governmental Affairs Committee**  
**“H1N1 Flu: Getting the Vaccine to Where It Is Needed Most”**  
**Washington, DC**  
**November 17, 2009**

Good afternoon. We hold this hearing on the H1N1 flu against the backdrop of two crucial numbers going the wrong way – more flu deaths than previously realized and fewer vaccine doses than originally promised.

This has led to understandable public frustration and anger mixed with confusion over just who should get vaccinated, with states and even individual cities and counties creating different priority lists. It has also led, I'm afraid, to some of the highest risk individuals, such as pregnant women and children with asthma waiting in those long lines for vaccine shots that ultimately were not available. And it has created anxiety, sometimes fear, among parents going on wild goose chases, trying to get vaccine for their children their government says they need but that they, the parents, can't find.

As I said in our previous hearings, I am very grateful for the work that Administration officials have done since the H1N1 virus appeared in April. Particularly, the H1N1 vaccine was developed in record time and safely.

And I know how hard each of you and your colleagues have been working since the onset of this global epidemic, but with so many eligible Americans still unable to get the vaccine, a good situation has turned bad. I worry that we are undermining confidence generally in the public health system, and that people most at risk are not only not getting the vaccine but have stopped trying.

Last week the Centers for Disease Control (CDC) released new estimates of the toll the H1N1 virus has taken to date, and they are significant: 22 million Americans struck ill by this virus, with 98,000 people needing hospitalization, and a little short of 4,000 people – including 540 children – have passed away either directly from H1N1 flu or from a combination of the flu and complications. That is a quadrupling of the previously reported death toll as it was understood in October.

Another set of estimates – the amount of vaccine available – has unfortunately been revised downward again and again since planning for the pandemic began in April.

And this, I believe, is what is really at the heart of what has caused so much frustration and fear, which I think was unnecessary.

Three months ago, CDC estimated the nation would have 120 to 160 million doses on hand by the end of October that would be used first to inoculate five target groups – pregnant women, caregivers of infants under six-months, health care providers, anyone between the ages of six months and 24 years, and high risk adults under the age of 65. These groups total a very large number – actually more than half the U.S. population – or about 160 million people – and

the consistent message to the public coming from HHS and CDC was that these initial target groups needed to get vaccinated.

So where did those numbers come from? The Advisory Committee on Immunization Practices (ACIP) is the group that identified those first priority groups. But I was interested to learn that it also generated a secondary and smaller list of the approximately 42 million most at risk in case vaccine availability fell short of what was planned for. Those in the most at-risk group include pregnant women, caregivers of infants under six months, health care workers, but then a smaller subset, children aged six months to four years, and high risk children aged 5-18.

Rear Admiral Anne Schuchat of the CDC described this targeted alternative at a July CDC press briefing as – and I quote – “a just in case scenario” that likely wouldn’t be needed but which we should have in our “back pocket.”

Then two months ago the “just in case” scenario became the reality we are dealing with today, as the estimate of available vaccine dropped to 85 million doses – and then by the end of October to under 27 million doses. Now there are about 42 million doses available, coincidentally exactly the number of Americans most at risk.

States were handed these two sets of guidelines and told to use their own discretion with respect to how to implement them. Some states opened their vaccination programs to everyone in the initial, large target group. Others, like my home state of Connecticut, took a conservative approach – starting with the smaller targeted subset and expanding the list as more vaccine becomes available.

But different states targeting different populations has sent a confusing message to the public about who needs to get the vaccines quickly. And there is little transparency into how and why these decisions are made.

**[CHART]:** This chart – based on CDC data – shows how significant the gap is between what would be needed to provide enough vaccine for the 160 million people in the broad priority groups – the 42 million people in the targeted subset – and what is actually available.

That was a recipe for the public outrage that has resulted.

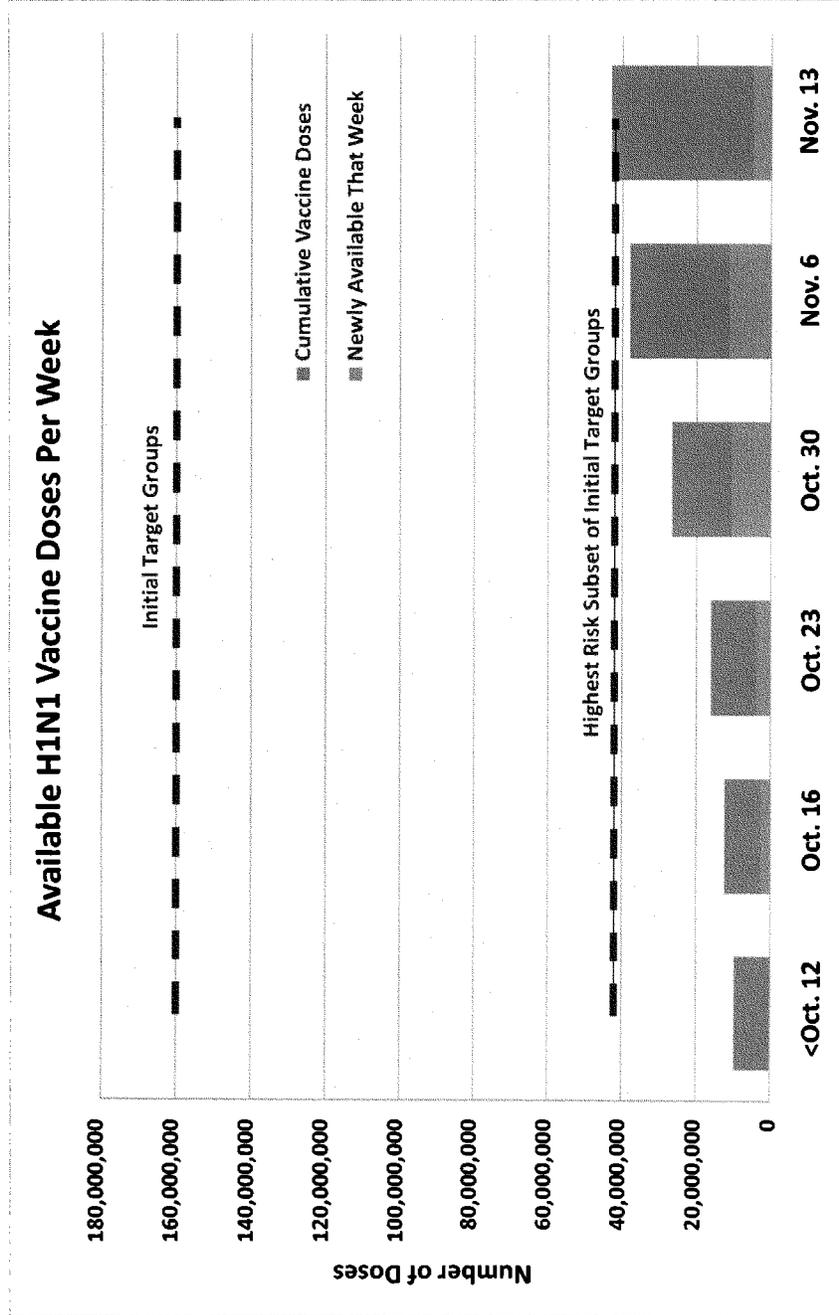
At our hearing last month, Health and Human Services Secretary Kathleen Sebelius expressed optimism that the problems with manufacturing and production of the vaccine that had been the obvious cause of the much smaller number than predicted had been resolved.

Things looked better two weeks ago when 11 million more doses were delivered, with another 8 million doses projected to be available last week. But by last Friday only about 5 million more were available.

And I want to ask today why we can’t accurately forecast supply just one week out or if something has happened again at the manufacturing facilities.

Senator Collins and I wrote a letter to Secretary Sebelius after our last hearing raising many of these many concerns. I did not find the Secretary's response to our letter satisfactory. She explained in some detail why HHS made key decisions along the way, but the response did not say that we have learned from this disappointing experience the American people have had or learned how to make it better. So today, I want to know what were the mistakes? How exactly are we adjusting our thinking going forward as this pandemic continues, and what are we learning that will make us better prepared for the next public health crisis?

Senator Collins?



Statement of  
Senator Susan M. Collins

**“H1N1 Flu: Getting the Vaccine to Where It Is Needed Most”**

Committee on Homeland Security and Governmental Affairs  
November 17, 2009

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**Thank you, Mr. Chairman, for holding this important hearing to focus on the continuing problems regarding the supply and distribution of the H1N1 flu vaccine.**

**This hearing is critical to peeling away the layers of misinformation and miscommunication that have hampered the federal government’s flu response strategy.**

**Many of our constituents, especially those most vulnerable to the virus, are frustrated and perplexed by the problems they face in getting vaccinated. Let me share the story of an 11-year-old boy named Brendon Stearns from Greenwood, Maine.**

**On October 27, Brendon wrote me a letter, describing his attempts to get the vaccine. He has two autoimmune diseases and asthma, placing him in a high-risk group for complications. Yet even after his mother called several possible sources - schools, the Maine CDC, doctors’ offices, hospitals, health clinics, and pharmacies - she could not find any vaccine available. Her persistence paid off when a source was found in Rockland, but that was a nearly six-hour round-trip drive from the family’s home in Greenwood.**

**I was dismayed to learn about the extraordinary effort this family had to undertake in order to get the vaccine for their high-risk child. Such extreme measures should not have been required. And it raises the troubling question: how many others just like Brendon are still waiting for their vaccination?**

**Despite consistent reassurances from the federal government that vaccine would be available for all that wanted it, the bottom line is that people like Brendon and his mother often have been left to fend for themselves. Scores of people in Maine are telling me similar stories... a veteran from Biddeford with compromised immunity due to a liver**

**Page 2 of 4**

**transplant...school nurses frustrated with last-minute changes from the CDC regarding vaccine availability.**

**What is the national strategy? Where was the plan? Why wasn't the plan altered when manufacturing problems first became evident? Instead of false assurances, why wasn't the federal government explaining the challenges with vaccine production and revising and clearly communicating a new vaccination strategy?**

**If I were to summarize the sentiments of these Mainers and so many others who have hit obstacle after obstacle in trying to obtain the H1N1 flu vaccine, I would choose one word: "frustrated."**

**Parents are frustrated that they cannot get vaccine for their children.**

**Doctors and nurses are frustrated because they cannot give their patients accurate timelines for vaccine arrival.**

**State and local officials are frustrated. They cannot plan a cohesive community response because the promised supply of vaccine often doesn't arrive on time - if at all.**

**Americans across the nation are frustrated because they cannot take recommended steps to help protect themselves or their family's health.**

**For another example, let's look across the country to California. The website for the Department of Public Health for San Francisco has a section called "Frequently Asked H1N1 Swine Flu Vaccine Questions."**

**Question: My pediatric office has live virus vaccine, when will they get the injectable vaccine?**

**Answer: The Health Department has no way of knowing that, and neither does your doctor's office. All orders are being filled on a random basis.**

**Question: I go to an internal medicine doctor for my care, when will she have vaccine?**

**Answer: This is unknown. At the rate vaccine has been trickling in, it could be in 1-2 months.**

**Page 3 of 4**

**Question: Why does the doctor's office across the street from where I take my children have vaccine, but my children's doctor's office doesn't?**

**Answer: Orders are being filled on a random basis. There is no way to predict who will get what and when.**

**Question: What am I supposed to do if I'm in a high risk category and I can't find any vaccine.**

**Answer: Take comfort in the fact that you are not alone...It remains unclear to all involved when the full supply of vaccine will be in place so please remain patient and calm and know that the whole country is experiencing the same wait.**

**While high-risk veterans in Maine have been unable to get vaccinated at the VA, we learn that terrorist detainees at Guantanamo Bay may be getting the vaccine ahead of Americans in priority at-risk groups. We learn that executives at bailed-out banks, such as Goldman Sachs and Citigroup, may get the vaccine ahead of children and pregnant women.**

**Just last month, this Committee held a hearing to examine the government's efforts. When we asked about vaccine availability, we received rosy reassurances by the Administration witnesses about the supply of H1N1 vaccine. Secretary Sebelius said, "By early November we are confident that vaccine is going to be far more widely available. There is enough vaccine, and will be, to vaccinate every American who wants to be vaccinated, and we are pushing it out as quickly as we can."**

**Well, it's mid-November, and we know that supply production is still lagging behind those repeated assurances.**

**Only after our October 21 hearing did the truly dire nature of the vaccine shortage come into clear focus. Following that hearing, Senator Lieberman and I sent letters to Secretary Sebelius asking for her prompt reply to specific questions. What we received in response were generalizations and non-answers.**

**The Administration needs to do a far better job working with state and local public health officials who can then set attainable goals to ensure that the vaccine is distributed to the most vulnerable groups.**

**I'm interested to hear from the witnesses about efforts the government should take to correct the current problem and to develop a long-term**

**Page 4 of 4**

**strategy, such as expediting the development of cell-based technology plants for vaccine manufacturing.**

**Americans - like Brendon - deserve answers. H1N1 may well resurge, perhaps in a more virulent form, next year. In any event, it won't be the last pandemic we face.**

**###**

**STATEMENT OF SEN. PAUL G. KIRK, JR.**  
**Committee on Homeland Security and Government Affairs**  
**H1N1 Flu: Getting the Vaccine to Where It Is Most Needed**  
*Tuesday, November 17, 2009*

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Chairman Lieberman, I commend you for calling this hearing today. The continuing delays in H1N1 vaccine production and distribution are generating significant fear among Americans, especially parents of young children, because these children are among the most vulnerable to the virus.

The number of persons in high-risk populations is as many as half of the nation's people, and it far exceeds the 40 million doses that have been shipped to the states. Massachusetts has received fewer than 900,000 doses of the vaccine, and we've already had 1500 cases of H1N1, including 13 deaths. Many of us are seriously concerned that far more individuals will come down with the virus, and far more lives will be lost, before sufficient quantities of the vaccine arrive.

At the Committee's hearing on the issue last month, it was made clear that our federal agencies are working in close coordination on the H1N1 response, which makes sense. But production delays have repeatedly prevented the government from meeting its targets for vaccine distribution, and that has been a major black eye for our response.

Obviously, it's difficult to predict timelines for vaccine production and distribution, and there's often a lag time in developing a new vaccine. But I hope there's more we can do in the near term to increase production and give priority to those who are at the gravest risk, such as children and pregnant women with underlying respiratory conditions.

Over the longer term, we need to do more to reduce our reliance on these kinds of essential vaccine imports. It's no surprise that the Canadians, for example, who are also combating the H1N1 outbreak, are reluctant to export their vaccines until their own population is served.

Hopefully, we can find ways to expedite vaccine development and production, but to do so will require the government to take another look at pandemic preparedness. That review should include whether investments are needed for surge capacity for vaccines for pandemic responses.

I look forward to our witnesses' testimony, and, again, I commend the Chairman for holding this hearing.

November 23, 2009

Senator Paul Kirk  
188 Russell Senate Office Bldg.  
Washington, DC 20510

Senator Kirk,

How was your week? Let me tell you about my families' week. Less than two weeks ago, I had a healthy 50 year old brother. Jim Shea was a husband, father of 8 year old twins, a brother to three sisters and the only son of my parents. Less than two weeks ago, we would not have believed that he would contract H1N1 and become seriously ill.

Less than two weeks ago, we would not have believed that he would be put on a respirator less than 12 hours after going into the hospital with flu symptoms. Less than two weeks ago, we would not have believed he would have strep and pneumonia due to H1N1 and, less than two weeks ago, we would not have believed his kidneys would fail, his liver would stop functioning, he would experience heart complications, cardiac arrest and, less than two weeks ago, we would not have believed he would die from H1N1. My brother was in one of the finest hospitals in this country and they could not save him from H1N1. However, all it would have taken to prevent this was the H1N1 vaccine. Less than two weeks ago, my brother, like you, a husband and father and son, was carrying on with his life.

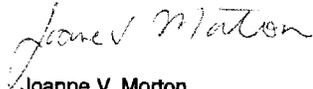
What has happened? When did our country lose the ability to perform a simple task? It is not acceptable that in 2009, our country could not have enough H1N1 flu vaccines to vaccinate our people. It should not be acceptable that the process to produce the vaccine has taken so long. It should not be acceptable in this day and age and in OUR country that a healthy husband, father, son and brother dies from the preventable H1N1 flu. Do you want to be the one to explain this to my brother's 8 year old twins?

We knew H1N1 was coming. We know many have still not been vaccinated including our family. Like many other families, we are patiently waiting for enough to be available. It is not acceptable the process is slow with the manufacturing of the vaccine. It is not acceptable that in 2009, everyone, every man, woman and child is still not vaccinated for H1N1. How do my brother's children keep faith in this country as they grow up now without a father? How do they reconcile that their father died from a preventable flu in our country in 2009? My brother did not die a heroic death fighting for his country or saving a child from a burning building but instead, died fighting a heroic battle against a preventable flu. It does not make sense and will not ever make sense.

I write this letter because I believe something positive can come of this tragedy. Less than two weeks ago, I would not have believed I would be writing you this letter. The only way this will ever be barely acceptable is to make my brother the last unnecessary death from the H1N1 flu. The only way this will be barely acceptable is to enlist the help now of any and all manufacturers that will help speed the process produce this vaccine for everyone, immediately. In this country, in 2009, we should have a surplus of the

vaccine not shortage. The only way this will be barely acceptable is to not have my brother's death be in vain but instead, be a memorial to his wife, children and family that he paved the way for all to be vaccinated from H1N1. This should not have happened.

Sincerely,



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cc: Pres. Barack Obama  
V.P. Joe Biden  
Governor Deval Patrick  
Sen. John Kerry



**Testimony before the  
Committee on Homeland Security and  
Governmental Affairs  
United States Senate**

**H1N1 Flu: Getting the Vaccine to Where It  
Is Most Needed**

**Rear Admiral Anne Schuchat, M.D.**  
Assistant Surgeon General  
Director, National Center for Immunization and Respiratory  
Diseases (NCIRD)  
Centers for Disease Control and Prevention  
U.S. Department of Health and Human Services

**For Release upon Delivery  
Expected at 2:30 p.m.  
November 17, 2009**

Chairman Lieberman, Ranking Member Collins, members of the Committee, thank you for this opportunity to update you on the public health challenges of 2009 H1N1 influenza.

The Centers for Disease Control and Prevention (CDC) and our colleagues throughout the Department of Health and Human Services (HHS) are working in close partnership with many parts of the federal government, as well as with states and localities, under a national preparedness and response framework for action that builds on the efforts and lessons learned from the past few months, this previous spring and influenza preparedness trainings conducted during the last several years. Working together with governors, mayors, tribal leaders, state and local health departments, the medical community and our private sector partners, we have been monitoring the spread of H1N1 and facilitating prevention and treatment, including implementing a vaccination program. CDC also has deployed staff, both domestically and globally, to assist in epidemiologic investigation of the virus and support state, local and territorial health departments with the H1N1 mass vaccination campaign.

Influenza is probably the least predictable of all infectious diseases, and the 2009 H1N1 pandemic has presented considerable challenges—in particular the delay in production and delivery of a vaccine, in part because of the slow growth of the virus during the manufacturing process. Today I will update you on the overall situation, provide an update on vaccination status, and discuss other steps we are taking to address these challenges.

**Tracking and Monitoring Influenza Activity**

One major area of effort is the tracking and monitoring of influenza activity, which helps individuals and institutions monitor and understand the impact of the 2009 H1N1 virus. Since the initial spring emergence of 2009 H1N1 influenza, the virus has spread throughout the world. H1N1 was the dominant strain of influenza in the southern hemisphere during its winter flu season. Data about the virus from around the world—much of it collected with CDC assistance—have shown that the circulating pandemic H1N1 virus has not mutated significantly since the spring, and the virus remains very closely matched to the 2009 H1N1 vaccine. This virus also remains susceptible to the antiviral drugs oseltamivir and zanamivir, with very rare exception.

Unlike a usual influenza season, flu activity in the United States continued throughout the summer, at summer camps and elsewhere. More recently, we have seen widespread influenza activity in 48 states; any reports of widespread influenza this early in the season are very unusual. Visits to doctors for influenza-like illness as well as flu-related hospitalizations and deaths among children and young adults also are higher than expected for this time of year, and higher than have been observed at any time in many recent flu seasons. We are also already observing that more communities are affected than those that experienced H1N1 outbreaks this past spring and summer.

Almost all of the influenza viruses identified so far this season have been 2009 H1N1 influenza A viruses. However, seasonal influenza viruses also may cause illness in the upcoming months—getting one type of influenza does not prevent you from getting another type later in the season.

Because of the current H1N1 pandemic, several additional systems have been put in place and existing systems modified to more closely monitor aspects of 2009 H1N1 influenza. These include the following:

*Enhancing Hospitalization Surveillance:* CDC has greatly increased the capacity to collect detailed information on patients hospitalized with influenza. Using the 198 hospitals in the Emerging Infections Program (EIP) network and 6 additional sites with 76 hospitals, CDC monitors a population of 25.6 million to estimate hospitalization rates by age group and monitor the clinical course among persons with severe disease requiring hospitalization.

*Expanding Testing Capability:* Within 2.5 weeks of first detecting the 2009 H1N1 virus, CDC had fully characterized the new virus, disseminated information to researchers and public health officials, and developed and begun shipping to states a new test to detect cases of 2009 H1N1 infection. CDC continues to support all states and territories with test reagents, equipment, and funding to maintain laboratory staff and ship specimens for testing. In addition, CDC serves as the primary support for public health laboratories conducting H1N1 tests around the globe and has provided test reagents to 406 laboratories in 154 countries. It is vital that accurate testing continue in the United States and abroad to monitor any mutations in the virus that may indicate increases in infection severity, resistance to antiviral drugs, or a decrease in the match between the vaccine strain and the circulating strain.

*Health Care System Readiness:* HHS is also using multiple systems to track the impact the 2009 H1N1 influenza outbreak has on our health care system. HHS is in constant communication with

state health officials and hospital administrators to monitor stress on the health care system and to prepare for the possibility that federal medical assets will be necessary to supplement state and local surge capabilities. To date, state and local officials and health care facilities have been able to accommodate the increased patient loads due to 2009 H1N1, but HHS is monitoring this closely and is prepared to respond quickly if the situation warrants.

*Implementing a Flu-related School Dismissal Monitoring System:* CDC and the U.S. Department of Education (ED), in collaboration with state and local health and education agencies and national non-governmental organizations, have implemented a flu-related school dismissal monitoring system for the 2009-2010 school year. This monitoring system generates a verified, near-real-time, national summary report daily on the number of school dismissals by state across the 130,000 public and private schools in the United States, and the number of students and teachers impacted. The system was activated August 3, 2009. This has helped us to calibrate our messages and guidance and may have contributed to the smaller number of school closings seen in the fall relative to those seen in the spring.

#### **Providing Science-Based Guidance**

A second major area of effort in support of individuals and institutions is to provide science-based guidance that allows them to take appropriate and effective action. Slowing the spread and reducing the impact of 2009 H1N1 and seasonal flu is a shared responsibility. We can all take action to reduce the impact flu will have on our communities, schools, businesses, other community organizations, and homes this fall, winter, and spring.

There are many ways to prevent respiratory infections and CDC provides specific recommendations targeted to a wide variety of groups, including the general public, people with certain underlying health conditions, infants, children, parents, pregnant women, and seniors. CDC also has provided guidance to workers and in relation to work settings, such as health care workers, first responders, and those in the swine industry, as well as to laboratories, homeless shelters, correctional and detention centers, hemodialysis centers, schools, child care settings, colleges and universities, small businesses, and federal agencies.

With the holidays coming up, reducing the spread of 2009 H1N1 influenza among travelers will be an important consideration.

CDC quarantine station staff respond to reports of illness, including influenza-like illness when reported, in international travelers arriving at U.S. ports of entry. Interim guidance documents for response to travelers with influenza-like illness, for airline crew, cruise ship personnel and Department of Homeland Security port and field staff have been developed and posted online. As new information about this 2009 H1N1 influenza virus becomes available, CDC will evaluate its guidance and, as appropriate, update it using the best available science and ensure that these changes are communicated to the public, partners, and other stakeholders.

In preparation for the upcoming months when we expect many families and individuals to gather for the holidays, we are preparing to launch a national communications campaign to encourage domestic and international travelers to take steps to prevent the spread of flu. Plans are to display public advertisements with flu prevention messages in ports of entry and various other

advertising locations, such as newspapers and online advertisements, both before and during the upcoming holiday travel season.

**Supporting Shared Responsibility and Action through Enhanced Communication**

A third major area of effort is to support shared responsibility and action through enhanced communication to individuals. Our recommendations and action plans are based on the best available scientific information. CDC is working to ensure that Americans are informed about this pandemic and consistently updated with information in clear language. The 2009 H1N1 pandemic is a dynamic situation, and it is essential that the American people are fully engaged and able to be part of the mitigation strategy and overall response. CDC will continue to conduct regular media briefings, available at [flu.gov](http://flu.gov), to get critical information about influenza to the American people.

Some ways to combat the spread of respiratory infections include staying home when you are sick and keeping sick children at home. Covering your cough and sneeze and washing your hands frequently will also help reduce the spread of infection. Taking personal responsibility for one's health will help reduce the spread of 2009 H1N1 influenza and other respiratory illnesses.

CDC is communicating with the public about ways to reduce the spread of flu in more interactive formats such as blog posts on the Focus on Flu WebMD blog, radio public service announcements, and podcasts.

Through the CDC INFO Line, we serve the public, clinicians, state and local health departments and other federal partners 24 hours/day, 7 days/week, in English and Spanish both for phone and email inquiries. Our information is updated around the clock so we are well positioned to respond to the needs and concerns of our inquirers. Our customer service representatives get first-hand feedback from the public on a daily basis. In addition to the H1N1 response, we continue to provide this service for all other CDC programs.

#### **Prevention through Vaccination**

A fourth major area of effort is prevention through vaccination. Vaccination is our most effective tool to reduce the impact of influenza. Working in close partnership with industry, HHS has led the process of developing a safe and effective 2009 H1N1 influenza vaccine, but the delivery of vaccine to the public has not been as rapid as hoped or initially estimated. CDC, in collaboration with the Food and Drug Administration (FDA), characterized the virus, identified a candidate vaccine strain, and our HHS partners expedited manufacturing, initiated clinical trials, and licensed four 2009 H1N1 influenza vaccines all within five months. The speed of this vaccine development was made possible due to investments made in vaccine advanced research and development and vaccine manufacturing infrastructure building through the office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) over the past four years, and in collaboration with CDC, the National Institutes of Health (NIH), and FDA. The rapid responses of HHS agencies, in terms of surveillance, viral characterization, pre-clinical and clinical testing, and assay development, were greatly aided by pandemic preparedness efforts for influenza pandemics set in motion by the H5N1 virus re-emergence in 2003, and the resources Congress provided for those efforts.

Pandemic planning had anticipated vaccine becoming available 6-9 months after emergence of a new influenza. In fact, 2009 H1N1 vaccination began in early October—just 5 months after the emergence of 2009 H1N1 influenza. Critical support from Congress resulted in \$1.44 billion for states and hospitals to support planning, preparation, and implementation efforts. States and cities began placing orders for the 2009 H1N1 vaccine on September 30th. The first vaccination with 2009 H1N1 influenza vaccine outside of clinical trials was given October 5th. Tens of millions of doses have become available for ordering, and millions more become available each week. Although the initial pace of vaccine delivery to the States has complicated the early immunization efforts, vaccine will become increasingly available over the weeks ahead, and will become more visible through delivery in a variety of settings, such as vaccination clinics organized by local health departments, healthcare provider offices, schools, pharmacies, and workplaces.

States have begun executing their plans to provide vaccine to targeted priority populations, and CDC continues to offer technical assistance to states and other public health partners as we work together to ensure the H1N1 vaccination program is as effective as possible. Although we had hoped to have more vaccine distributed by this point, we are working hard to get vaccine out to the public just as soon as we receive it.

H1N1 vaccines are manufactured by the same companies employing the same methods used for the yearly production of seasonal flu vaccines. H1N1 vaccine is distributed to providers and state health departments similarly to the way federally purchased vaccines are distributed in the

Vaccines for Children program. Two types of 2009 H1N1 vaccine are now available: injectable vaccine made from inactivated virus, including thimerosal-free formulations, and nasal vaccine made from live, attenuated (weakened) virus.

CDC's Advisory Committee on Immunization Practices (ACIP) has recommended that 2009 H1N1 vaccines be directed to target populations at greatest risk of illness and severe disease caused by this virus. On July 29, 2009, ACIP recommended targeting the first available doses of H1N1 vaccine to five high-risk groups comprised of approximately 159 million people; CDC accepted these recommendations. These groups are: pregnant women; people who live with or care for children younger than 6 months of age; health care and emergency services personnel; persons between the ages of 6 months through 24 years of age; and people from ages 25 through 64 years who are at higher risk for severe disease because of chronic health disorders like asthma, diabetes, or compromised immune systems. In addition, ACIP recommended that local public health authorities may want to prioritize a smaller group of people while supplies are limited, in which case the following groups who are at the highest risk for infection or severe illness should receive the vaccine before others: pregnant women, people who live with or care for children younger than 6 months of age, health care and emergency medical services personnel with direct patient contact, children 6 months through 4 years of age, and children 5 through 18 years of age who have chronic medical conditions. This subset of the five target groups comprises approximately 42 million persons in the United States. These recommendations provide a framework from which states can tailor vaccination to local needs.

Ensuring a vaccine that is safe as well as effective is a top priority. CDC expects that the 2009 H1N1 influenza vaccine will have a similar safety profile to seasonal influenza vaccine, which historically has an excellent safety track record. So far the reports of adverse events among H1N1 vaccination are generally mild and are similar to those we see with seasonal flu vaccine. We will remain alert, however, for the possibility of rare, severe adverse events that could be linked to vaccination. CDC and FDA have been working to enhance surveillance systems to rapidly detect any unexpected adverse events among vaccinated persons and to adjust the vaccination program to minimize these risks. Two primary systems used to monitor vaccine safety are the Vaccine Adverse Events Reporting System (VAERS), jointly operated between CDC and FDA, and the Vaccine Safety Datalink (VSD) Project, a collaborative project with eight managed care organizations covering more than nine million members. These systems are designed to determine whether adverse events are occurring among vaccinated persons at a greater rate than among unvaccinated persons. CDC has worked with FDA and other partners to strengthen these vaccine safety tracking systems and we continue to develop new ways to monitor vaccine safety, as announced earlier this week by the Federal Immunization Safety Task Force in HHS. In addition, based on the recommendation of the National Vaccine Advisory Committee (NVAC), HHS established the H1N1 Vaccine Safety Risk Assessment Working Group to review 2009 H1N1 vaccine safety data as it accumulates. This working group of outside experts will conduct regular, rapid reviews of available data from the federal safety monitoring systems and present them to NVAC and federal leadership for appropriate policy action and follow-up.

More than 36,000 people die each year from complications associated with seasonal flu. CDC continues to recommend vaccination against seasonal influenza viruses, especially for all people 50 years of age and over and all adults with certain chronic medical conditions, as well as infants and children. As of the fourth week in October, 89 million doses of seasonal vaccine had been distributed. It appears that interest in seasonal flu vaccine has been unprecedented this year. Manufacturers estimate that a total of 114 million doses will be brought to the U.S. market.

**Reducing the Burden of Illness and Death through Antiviral Distribution and Use**

In the spring, anticipating commercial market constraints, HHS deployed 11 million courses of antiviral drugs from the Strategic National Stockpile (SNS) to ensure the nation was positioned to quickly employ these drugs to combat 2009 H1N1 and its spread. In early October, HHS shipped an additional 300,000 bottles of the oral suspension formulation of the antiviral oseltamivir to states in order to mitigate a predicted near-term national shortage indicated by commercial supply data. In addition, the Secretary authorized the release of the remaining 234,000 bottles of pediatric Tamiflu® on October 29th. We will continue to conduct outreach to pharmacists and providers related to pediatric dosing and compounding practices to help assure supplies are able to meet pediatric demand for antiviral treatment, and we have updated our guidance relating to general antiviral use as new information has warranted. Finally, CDC and FDA have also worked together to address potential options for treatment of seriously ill hospitalized patients with influenza, including situations in which physicians may wish to use investigational formulations of antiviral drugs for intravenous therapy. The FDA issued an emergency use authorization (EUA) on October 23rd, 2009, for the investigational antiviral drug peramivir intravenous (IV) authorizing the emergency use of peramivir for the treatment of

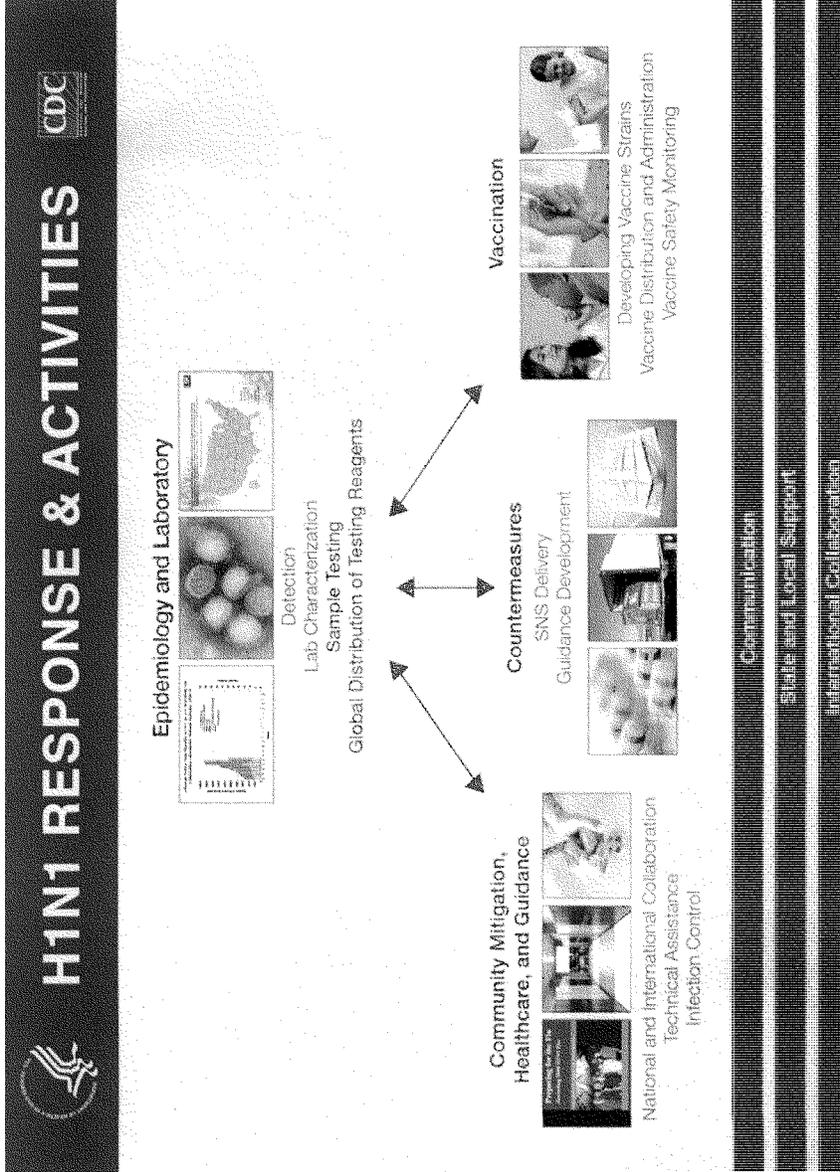
certain hospitalized adult and pediatric patients with confirmed or suspected 2009 H1N1 influenza infection. Physician requests for peramivir to be used under the EUA are managed through a CDC web portal.

**Closing Remarks**

CDC is working hard to limit the impact of this pandemic, and we are committed to keeping the public and the Congress fully informed about both the situation and our response. We are collaborating with our federal partners as well as with other organizations that have unique expertise to help CDC provide guidance to multiple sectors of our economy and society. There have been enormous efforts in the United States and abroad to prepare for this kind of challenge.

Our nation's current preparedness is a direct result of the investments and support of Congress over recent years, effective planning and action by Federal agencies, and the hard work of state and local officials across the country. We look forward to working closely with Congress as we address the situation as it continues to evolve in the weeks and months ahead.

Again, Mr. Chairman, thank you for the opportunity to participate in this conversation with you and your colleagues. I look forward to answering your questions.



	<p><b>Testimony</b> <b>Committee on Homeland Security and</b> <b>Governmental Affairs</b> <b>United States Senate</b></p>
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**Safeguarding our Nation: HHS  
Response to the H1N1 Outbreak**

*Statement of*  
**Nicole Lurie, MD, MSPH**  
*Assistant Secretary for Preparedness and Response*  
*U.S. Department of Health and Human Services*



**For Release on Delivery**  
**Expected at 2:30pm**  
**Tuesday, November 17, 2009**

Good afternoon Chairman Lieberman, Ranking Member Collins, and Members of the Committee. I am Dr. Nicole Lurie, the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS). As Secretary Sebelius emphasized in her testimony before the Senate in October, slowing the spread and reducing the impact of 2009 H1N1 is a shared responsibility, and we all need to plan for what would need to be done as the flu impacts our communities, schools, businesses, and homes this fall. I appreciate the opportunity today to discuss our role as well as some of the challenges and successes we have encountered in responding to the 2009 H1N1 influenza outbreak.

Before I go further, let me take the opportunity to thank you not only for the rapid congressional appropriations to respond to this current influenza threat but also for the foresight in providing significant resources since FY 2006 to lay the foundation for our Nation's pandemic preparedness. These resources have demonstrated a strong return on investment and have dramatically improved our ability to respond. However, our work in this area is far from done. We look forward to working with you and your congressional colleagues in the future to continue to build our response capabilities not only for an influenza virus but also the wide range of natural and manmade threats that we face.

**Overview of the Outbreak**

Since the initial spring outbreak of 2009 H1N1 influenza, this virus has triggered a worldwide pandemic, and was the dominant flu strain in the southern hemisphere during that hemisphere's winter flu season. Data about the virus from around the world have shown that the circulating pandemic H1N1 virus has not mutated significantly since the spring. The virus remains similar to the virus chosen for the 2009 H1N1 vaccine, and remains susceptible to the antiviral drugs oseltamivir (Tamiflu) and zanamivir (Relenza), with rare exception. As with seasonal influenza, persons with some chronic health disorders and pregnant women have a higher risk of severe disease. In contrast to seasonal influenza, elderly persons have proven less likely to contract the virus; nevertheless, many elderly persons who do contract the virus have had serious complications. Early treatment with antivirals is recommended for elderly persons as well as for pregnant women, others at high risk for complications, and for anyone who becomes seriously ill.

Unlike our typical seasonal flu, we continued to see flu activity in the United States over the summer, notably among school-aged children and young adults. More recently, we have seen widespread influenza activity in almost all states. Visits to doctors for influenza-like illness are much higher than levels expected for this time of the year.

Over the next several months, seasonal influenza viruses may circulate along with the 2009 H1N1 influenza virus, and it will not be possible to determine quickly if ill individuals have 2009 H1N1 influenza, seasonal influenza, or other respiratory conditions based on symptoms alone. Because of this, close monitoring of viruses in the United States will be critical to ensure that the best guidance about treatment and prevention of influenza can be provided.

**Office of the Assistant Secretary for Preparedness and Response (ASPR)**

The Pandemic and All-Hazards Preparedness Act (the Act) designated the HHS Secretary as the lead Federal official for public health and medical response to public health emergencies and incidents covered by the National Response Plan developed pursuant to section 502(6) of the Homeland Security Act of 2002, or any successor plan, and created the Assistant Secretary for Preparedness and Response. Under the Act, ASPR plays a pivotal role in coordinating emergency response efforts across the various HHS agencies and among our federal interagency partners.

**2009 H1N1 Task Force**

In July 2009, the White House National Security Staff (NSS) released the *National Framework for 2009 H1N1 Influenza Preparedness and Response (National Framework)* to ensure a coordinated and focused national strategy. In response, ASPR created the 2009 H1N1 Task Force to: coordinate and consolidate H1N1 strategic program activities; serve as the focal point for policy

coordination; and ensure that HHS's National Framework activities and accomplishments are reported to DHS according to NSS timelines.

The Task Force addresses the National Framework's four key capability "pillars:" surveillance, mitigation measures, vaccination, and communication and education. The Task Force meets regularly with me and the HHS Chief of Staff to review ongoing activities to ensure our successful execution of the National Framework strategy. The Task Force has closely collaborated with DHS to establish a Common Operating Picture (COP) for 2009 H1N1, a single display of relevant information to facilitate collaborative planning and to achieve situational awareness.

*ESF #8 Response Activities*

Under the National Response Framework, ASPR is responsible for coordinating the Emergency Support Function (ESF) #8 response – Public Health and Medical Services. ASPR provides the mechanism for coordinated federal assistance to supplement State, local, territorial and tribal resources in response to public health and medical care needs during an emergency.

Specifically with regard to the 2009 H1N1 influenza outbreak, ASPR coordinates the interagency public health and medical response activities through a series of twice-weekly ESF #8 calls. During these calls, HHS regional health administrators and regional emergency coordinators report updates on their

regions' pandemic influenza preparedness and response activities. Federal interagency partners also report their activities for group discussion and integration.

Other coordination activities include weekly calls between ASPR and the State health departments to discuss any challenges and issues that might necessitate federal assistance. ASPR has also conducted calls with intensive care physicians to better understand the clinical picture of patients requiring extensive care in hospitals and to share information and experience to help identify best practices to improve patient outcomes. One of our critical concerns is to prevent local healthcare system failures from becoming regional healthcare system failures. Proactive measures to support our local partners in preventing system failure include 1135 waivers to decompress overburdened hospitals and deploying federal assets (where necessary) including clinical staff, temporary medical facilities and any needed logistical support.

#### Hospital Preparedness

Since its inception in 2002, ASPR's Hospital Preparedness Program (HPP) has provided more than \$3 billion to fund the development of medical surge capacity and capability at the State and local level. HPP funds are awarded to State and territory departments of public health, which in turn fund projects at hospitals and other healthcare entities. As a result, hospitals can now communicate with other responders through interoperable communication systems; track bed and

resource availability using electronic systems; protect their healthcare workers with proper equipment; train their healthcare workers on how to handle medical crises and surges; develop fatality management, hospital evacuation, and alternate care plans; and coordinate regional training exercises.

As a result of Congress's investment in the Hospital Preparedness Program our hospitals are better prepared to respond to the current 2009 H1N1 outbreak. Since the inception of funding, pandemic influenza preparedness and development of alternative care sites have been two priorities of the HPP program. In 2007, \$75 million was awarded to States and territories specifically for pandemic influenza planning, including pandemic exercises and purchases of equipment, such as ventilators, that would aid in their response to a pandemic. Of the grantees receiving these funds, 79% conducted pandemic influenza exercises to hone their preparedness capabilities. In 2009, \$90 million was awarded from the Supplemental Appropriations Act, 2009 for purchase of personal protective equipment, such as N-95 respirators for healthcare workers, and to develop plans for alternative care sites. CDC has also been providing support to States for vaccine program implementation and to help State and local health departments.

HPP has required recipients to implement a system of bed counting, called the "Hospital Available Beds in Emergencies and Disasters" (HAVBED). This system requires reports of available beds, including a count of available adult and

pediatric general beds and ICU beds, to State and HHS emergency operations centers within four hours of request. For the past couple of months, HAvBED has been operational and collecting information from States about hospital status and has enhanced our 2009 H1N1 medical surge response.

Furthermore, based on the lessons learned from the spring 2009 H1N1 response, HAvBED was modified to also collect information on emergency department stress and hospital stress. ASPR worked with the HPP grantees, the American Hospital Association and private vendors to develop a core set of measures (including daily census counts and equipment shortages) for the level of stress on the healthcare system. Within 48 hours of receiving information, we have senior ASPR experts discuss and analyze data to determine if any hospitals are showing signs of stress or if there are indicators of equipment shortages. On occasions where the data indicates stress, we engage our Regional Emergency Coordinators to work with State health departments in conducting an investigation. To date, state and local officials have been able to accommodate the increased patient loads, but this is something we monitor very closely, and are prepared to respond quickly if the situation warrants. In addition, the declaration by the President of H1N1 as a national emergency, coupled with the Secretary's Declaration of a Public Health Emergency, allows us to temporarily waive legal provisions or modify certain Medicare, Medicaid, CHIP, and HIPAA requirements under the Secretary's waiver authority under Section 1135 of the Social Security Act. This authority can provide hospitals with additional flexibility

in certain circumstances to deal more effectively with patient surge rather than restrictive paperwork. This move has been welcomed by local hospitals many of whom can now make requests of the Centers for Medicare and Medicaid Services for 1135 waivers in anticipation of increased patient loads. These requests are reviewed within 24 hours and can be granted retroactively to the beginning of the emergency period (that is, back to October 23, 2009) if needed.

Other Activities

ASPR is working with the Society for Critical Care Medicine and has conducted a ventilator survey that will enable HHS to understand how many ventilators are available and where any regional shortages might exist. We are also working with professional organizations to train physicians in care of patients on ventilators.

The National Disaster Medical System (NDMS) has trained personnel to become vaccinators to assist State and local jurisdictions in that activity. Additionally, NDMS teams have received training on 2009 H1N1 influenza and are standing by, ready to assist States/locals in the delivery of care to pandemic influenza patients or to augment non-flu treatment needs so that hospitals can divert their internal resources to H1N1 if needed.

**Responding to H1N1**

Responding to 2009 H1N1 influenza has provided challenges and valuable lessons that will assist our response efforts going forward. As this emergency unfolded, it became clear that significant resources would be necessary to respond to the pandemic with potentially large impacts. Further, based on a number of factors such as state readiness and vaccine effectiveness, we would not be able to plan response requirements with certainty and thus, how resources would need to be allocated. As a result, we greatly appreciate the flexible funding that the Congress provided for these efforts.

As we learn from the experiences of 2009 H1N1, we look forward to working with you to improve strategies to ensure that our Nation has the right assets at the right time to minimize the health impacts of an influenza pandemic, hurricane or bioterrorism event. The timely access to a flexible response fund has provided us with a nimbleness to quickly augment capabilities – such as hiring personnel on the front line of public health – where the speed of our response translates to lives saved.

Now, I will briefly discuss both our response efforts and a few of the challenges we encountered in our vaccine research and development, antiviral stockpiling, situational awareness, private sector collaboration, and international assistance.

Vaccine Research and Development

ASPR's investment over the past six years in medical countermeasure advanced research and development enabled the Department to complete 2009 H1N1 vaccine development with unprecedented speed. ASPR's Biomedical Advanced Research and Development Authority (BARDA) has worked with industry to build and sustain a domestic manufacturing infrastructure. Under the *HHS Pandemic Influenza Plan* (November 2005), the Department's key goals for vaccine preparedness were:

- Stockpile enough pre-pandemic influenza vaccines to cover 20 million persons in the critical workforce;
- Develop sufficient domestic manufacturing capacity to produce pandemic vaccine for the entire U.S. population of just over 300 million persons within six months of pandemic onset.

To establish domestic pre-pandemic influenza vaccine stockpiles, BARDA supported the development and manufacture of vaccines against different H5N1 avian virus strains. Today, BARDA continues to support a secure supply of raw materials, including eggs for domestic manufacturing of seasonal and novel influenza vaccines and the development and manufacturing of novel influenza vaccine candidates for clinical evaluation. BARDA also provided cost-sharing support to expand the domestic influenza vaccine manufacturing infrastructure by retrofitting existing vaccine manufacturing facilities and building new cell-based influenza vaccine manufacturing facilities. This facility will be operational in

2010. Additionally, FDA was fully engaged with industry to substantially increase the number of US licensed seasonal influenza vaccine manufacturers and their overall production capacity, a necessary infrastructure for pandemic vaccine development and production. It was through the licensed seasonal influenza vaccine framework that we were able to license and rapidly make available H1N1 vaccine.

The rapid responses of HHS agencies, including CDC, the National Institutes of Health, and the Food and Drug Administration, in terms of surveillance, viral characterization, pre-clinical and clinical testing, and assay development, were greatly aided by preparedness efforts for influenza pandemics set in motion by the H5N1 outbreak in 2003. Stockpiling for pandemic preparedness began in 2004, with H5N1 vaccine (23 million doses). In 2005 and 2006, the first six contracts for cell-based vaccines were initiated with manufacturers at a cost of \$1.3 billion. In 2007, two manufacturers were contracted for work on adjuvants, which are vaccine-boosting compounds (\$137.5 million). Throughout, clinical studies have been supported by ASPR/BARDA and the National Institutes of Health/ National Institute of Allergy and Infectious Diseases (NIH/NIAID).

These initial activities to prepare for H5N1 provided valuable lessons that have informed our efforts to respond to the current 2009 H1N1 outbreak. We learned, for example, that coordination between ASPR/BARDA, CDC, NIH/NIAID and

FDA was necessary to learn about the immunogenic properties of the virus and to conduct clinical trials. Working with our industry partners, we learned that, just as for seasonal influenza vaccines, one dose of the H1N1 vaccine induces a response that is likely to be protective in adults and older children. We also learned that vaccine distribution through Points of Distribution (POD) should not be the only option considered. Instead, we need to develop our planning and contractual relationships to allow for flexible distribution--in this case, through a third-party--to 150,000 State-specified locations.

Since September 30, when the 2009 H1N1 vaccine was first made available to states to distribute, the number of doses that has been produced, distributed, and administered has grown steadily, and states are executing their plans for providing vaccine to high-priority populations. Our goal is to ensure that everyone who wants to get vaccinated will ultimately be able to do so. While modest amounts of vaccine have been made available ahead of schedule, poor production yields with the initial vaccine strains; late completion of seasonal influenza vaccine manufacturing; and equipment failures on new production lines have caused significant delays in the manufacturers' timelines. In addition, one country where vaccine is manufactured claimed priority for their vaccine, resulting in a reduced amount of anticipated H1N1 vaccine available to the US. These delays are affecting both the U.S. and global H1N1 vaccine supplies.

Manufacturers assure us they are taking active steps to overcome the remaining challenges, and we are doing all in our power to help them.

Moreover, BARDA conducts regular site visits to the vaccine manufacturers and constantly monitors the progress of every lot produced, working to make up ground wherever possible. We also now have full time staff at two of the facilities to monitor and assist in addressing any problems that may occur. FDA has been actively involved in the review and approval of new fill and finish facilities to increase capacity. Finally, on October 29, Secretary Sebelius personally spoke with the CEOs of each of the five manufacturers to emphasize the importance of accelerating production in the coming weeks, and I had additional calls with the CEOs last week.

Our experience with the ups and downs of the vaccine manufacturing process has made clear the need to enhance our country's vaccine manufacturing capability. Going forward, HHS planning efforts will continue to support the advanced development of seasonal and pandemic influenza vaccines. In 2005 and 2006, the first six contracts for advanced development of cell-based influenza vaccines were initiated. Several of these contractors have made significant advances toward U.S. licensure of their cell-based influenza vaccines. In 2008, one of these contractors started to build a new state-of-the-art cell-based influenza vaccine manufacturing facility with a surge production capacity of 150 million doses of pandemic vaccine in six months using HHS/ASPR

support. Additionally, HHS is supporting the advanced development of a recombinant influenza vaccine, which promises to have a shorter timeframe for production of pandemic vaccines and expects to fund development of more recombinant vaccines soon. HHS also provided cost-sharing support to expand the domestic influenza vaccine manufacturing infrastructure by retrofitting existing domestic vaccine manufacturing facilities, securing year-round supply of eggs and other supplies for existing U.S.-based egg-based facilities, and supported the construction of new U.S.-based cell-based influenza vaccine manufacturing facilities. These investments will advance U.S. pandemic preparedness goals and decrease dependence on foreign manufacture of influenza vaccines.

#### Antiviral Stockpiling

Under the *HHS Pandemic Influenza Plan*, HHS was required to:

- Establish national influenza antiviral drug stockpiles to treat 25 percent of the U.S. population during a pandemic, plus an immediate readiness cache of 6 million treatment courses for containment at pandemic onset;
- Support the advanced development of new and promising influenza antiviral drugs toward U.S. approval; and
- Boost U.S.-based production of antiviral drugs.

To accomplish these mandates, ASPR awarded contracts in 2004-2007 totaling more than \$924 million to establish and coordinate the federal and State pandemic stockpiles of antiviral drugs. We procured 50 million treatment courses for storage in the Strategic National Stockpile (SNS) by the end of 2007, completing the federal contribution to the antiviral goal. Additionally, using funding provided by Congress, ASPR subsidized States in their purchase of 25 million treatment courses of antivirals towards the 31 million treatment course goal for State stockpiles.

In the spring, anticipating commercial market constraints, HHS deployed 11 million courses of antiviral drugs from the Strategic National Stockpile (SNS) to ensure the nation was positioned to quickly employ these drugs to combat H1N1 and its spread. This action has been effective in allowing the nation to deal with spot shortages of antiviral drugs and limitations on supplies of products targeted for young children, including liquid preparations authorized for emergency use in infants less than 1 year of age. To replenish the SNS, HHS purchased 13 million treatment courses (\$260 million) of Tamiflu® (10.4 million treatment courses) and Relenza® (2.6 million treatment courses). In October, HHS made available to states an additional 300,000 regimens of the antiviral pediatric oral suspension to mitigate a predicted near-term national shortage indicated by commercial supply data.

To support antiviral development and manufacturing ramp-up activities, BARDA awarded a contract in 2007 for \$102.7 million for advanced development and domestic industrialization of a new influenza antiviral drug. Beginning in 2008, BARDA also solicited and awarded additional contracts for new and combination influenza antiviral drugs. These efforts directly benefited pediatric and critically ill populations.

We know that antiviral resistance is a threat. So our acquisition strategy for additional antivirals needed to be flexible. A lesson learned from the 2009 H1N1 outbreak is that rare cases of H1N1 have been Tamiflu resistant. As a result, ASPR has increased efforts to stockpile an alternative antiviral, Relenza. We also know from this outbreak that children are disproportionately affected by 2009 H1N1 influenza, leading us to procure more pediatric courses of antivirals.

Another challenge presented by 2009 H1N1 influenza is the treatment of critically ill individuals, who potentially may require an intravenous antiviral formulation. Currently there are no influenza antiviral drugs licensed for parenteral use (such as I.V.), and further research is important to determine optimal therapy in this setting. Since January 2007, HHS has supported the advanced development of a new antiviral drug, Peramivir, which may be administered intravenously to hospitalized influenza patients. Intravenous administration may provide more dependable dosing for those critically ill patients who have seriously limited ability to absorb drugs given through the gastrointestinal tract, and it is hoped they

might offer a clinical benefit for that reason. On October 23, an Emergency Use Authorization was issued by the FDA for the utilization of Peramivir to treat critically ill patients with H1N1 virus infections. In addition, intravenous formulations of two other antiviral drugs, oseltamivir and zanamivir, for which other formulations are already approved, are being studied. ASPR is procuring intravenous (I.V.) influenza antiviral drugs for stockpiling to be used under Emergency Use Authorization.

#### Situational Awareness

Situational awareness is an essential component of any incident response. During the 2009 H1N1 influenza response, HHS worked very closely with the Department of Homeland Security (DHS) to develop a National Situation Report (SitRep) which is then inserted into the Homeland Security Information Network (HSIN). Working cooperatively, DHS and HHS have modified the SitRep to accurately reflect public health and medical issues. HHS has also been working with DHS to enable State and local public health officials to gain access to the HSIN so they can maintain their situational awareness.

#### Public-Private Sector Collaboration

HHS has engaged many private sector partners in a series of problem-solving dialogues related to the vaccine dispensing program. The Association of State and Territorial Health Officials (ASTHO) worked with ASPR to convene a series of meetings with America's Health Insurance Plans (AHIP), individual insurers,

American Pharmacists Association, retail pharmacy chains, American Medical Association (AMA), National Vaccine Program Office, and other State and federal partners. The private sector demonstrated a firm commitment to working through complex issues of vaccine administration, billing processes, and other policy issues that would facilitate a successful vaccine campaign with the goal of providing easy access to the 2009 H1N1 influenza vaccine for every person in the United States who wants it.

Many issues related to vaccine administration, including billing and payment issues, were raised. Partnerships with the HHS Centers for Medicare & Medicaid Services and the AMA yielded the development of specific vaccine codes, and unique vaccine administration codes for both Medicare recipients and the privately insured. In addition, the health insurers and pharmacies agreed upon a set of principles for billing practices and payment procedures and developed associated draft templates to support State vaccine program consistency.

#### International Assistance

There is broad international recognition that the 2009 H1N1 pandemic is a global health challenge. Millions of people around the world have been affected, thousands have died and the virus continues to spread across international borders. Like most diseases, 2009 H1N1 infection knows no borders. The health of the American people is inseparable from the health of people around the world. Early in the outbreak, HHS and other federal agencies received

multiple requests for international assistance. HHS has provided 769 laboratory and diagnostic kits to 147 countries, 400,000 treatment courses of antivirals to Mexico and 420,000 treatment courses to the Pan American Health Organization to provide assistance to Latin America and the Caribbean. Similarly, the U.S. Government has received requests for more than 30 million doses of vaccine from 21 countries. Recognizing the needs of developing countries, President Obama committed to make 10 percent of the US 2009 H1N1 vaccine supply available to them through the World Health Organization (WHO). Vaccine will be donated on a rolling basis, as it becomes available, in order to assist countries that will not otherwise have direct access to the vaccine. We are taking this action in concert with international partners: Australia, Brazil, France, Italy, New Zealand, Norway, Switzerland, Japan, Germany, and the United Kingdom.

On October 5, we met with the Governments of Mexico and Canada to review current 2009 H1N1 efforts and decided to re-institute the North American Plan for Avian and Pandemic Influenza Coordinating Body to ensure continued international coordination in the areas of human health, animal health, border issues and emergency management. On October 31, Secretary Sebelius discussed efforts to coordinate donor contributions, maximize the impact of our collective efforts, and mitigate the effects of this pandemic on the poorest regions of the world with the World Health Organization (WHO) Director General, United Nations System Influenza Coordinator (UNSIC), United Nations Secretary General, and United Nations Children's Fund (UNICEF) Executive Director.

**Conclusion**

I want to assure the Committee that the Administration is taking the public health challenges of 2009 H1N1 seriously and is implementing a comprehensive strategy to monitor and address this influenza outbreak throughout the fall and winter. HHS continues to work in close partnership with virtually every part of the federal government under a national preparedness and response framework for action that builds on the efforts and lessons learned from this spring.

Working together with governors, mayors, tribal leaders, state and local health departments, the medical community, and our private sector partners, the federal government has been actively implementing a vaccination program and continues to revise and refine our pandemic influenza plans and activities based on new data and information.

It is important to reiterate that our current level of preparedness and subsequent ability to respond is a direct result of the investments and support of Congress; the hard work of State, local, tribal, and territorial public health officials; and our partners in the private and not-for-profit sectors. Building strong systems to track and monitor seasonal influenza has allowed us to closely monitor the impact of this novel virus on our communities.

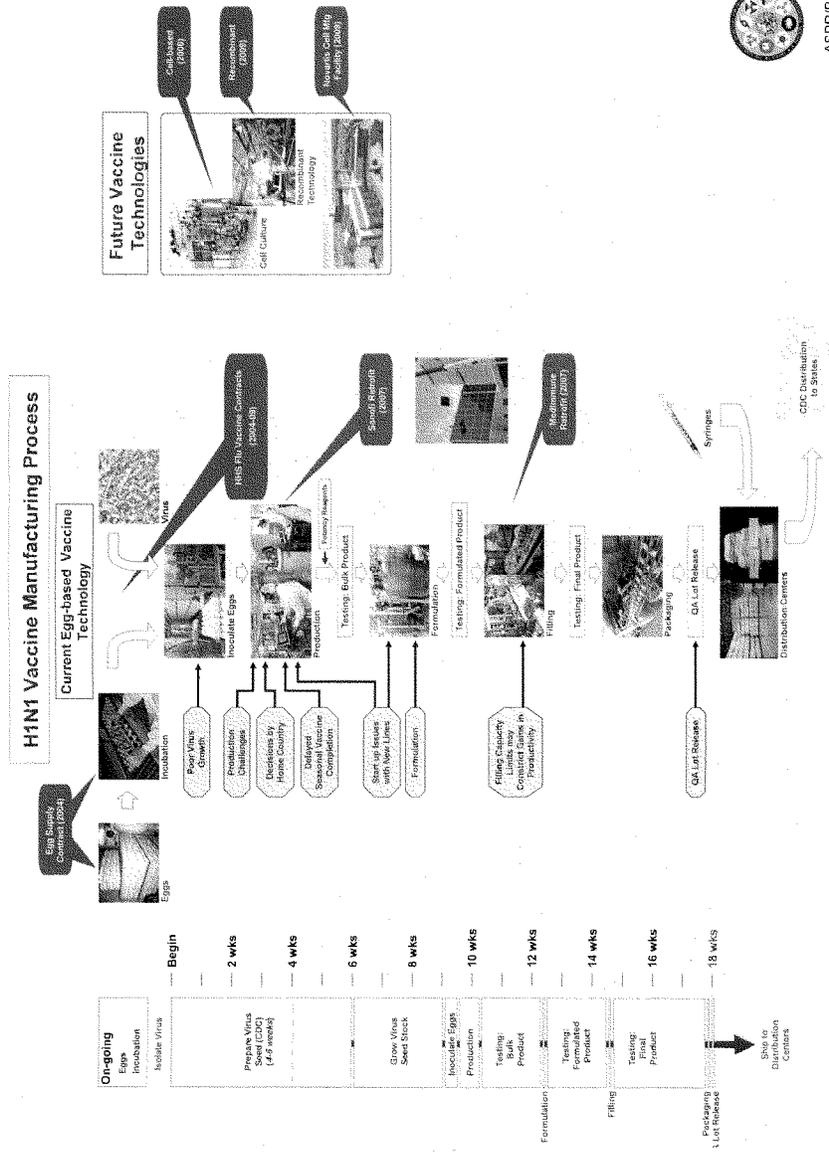
Our Nation's investment in public health infrastructure, particularly at the state and local levels, remains a critical challenge that has real life consequences.

Today, these consequences are impacting our communities, our schools, our workplaces and our homes.

Investments in science and the public health infrastructure will enable us to better prepare and respond to threats, such as 2009 H1N1, that arise in the future. For instance, the President's 2010 budget includes funding for advanced development of antiviral drugs and invests in new vaccine technology. This will advance our on-going commitments to developing new cell-based and recombinant vaccine production methods and help complete a domestic cell-based production facility, currently under construction here in the U.S. In addition, our work on new antivirals and important medical devices, including rapid diagnostics, continues to yield exciting results. These investments hold the promise of more effective treatments that can be developed over shorter timeframes and made available more quickly to families and individuals. It is also critical to increase investments in our State and local health departments, which have been chronically underfunded. We have made great strides in leveraging information technology to enhance surveillance of diseases threats, but need to increase our support for building the workforce of epidemiologists and other public health specialties that are vital to preventing, identifying and containing outbreaks. We also must ensure that we have the ability on the ground to reach at-risk populations with core public health interventions, such as communication strategies designed to mitigate the spread of disease and clearly define the risks of an emerging threat. This will pay dividends with more resilient communities

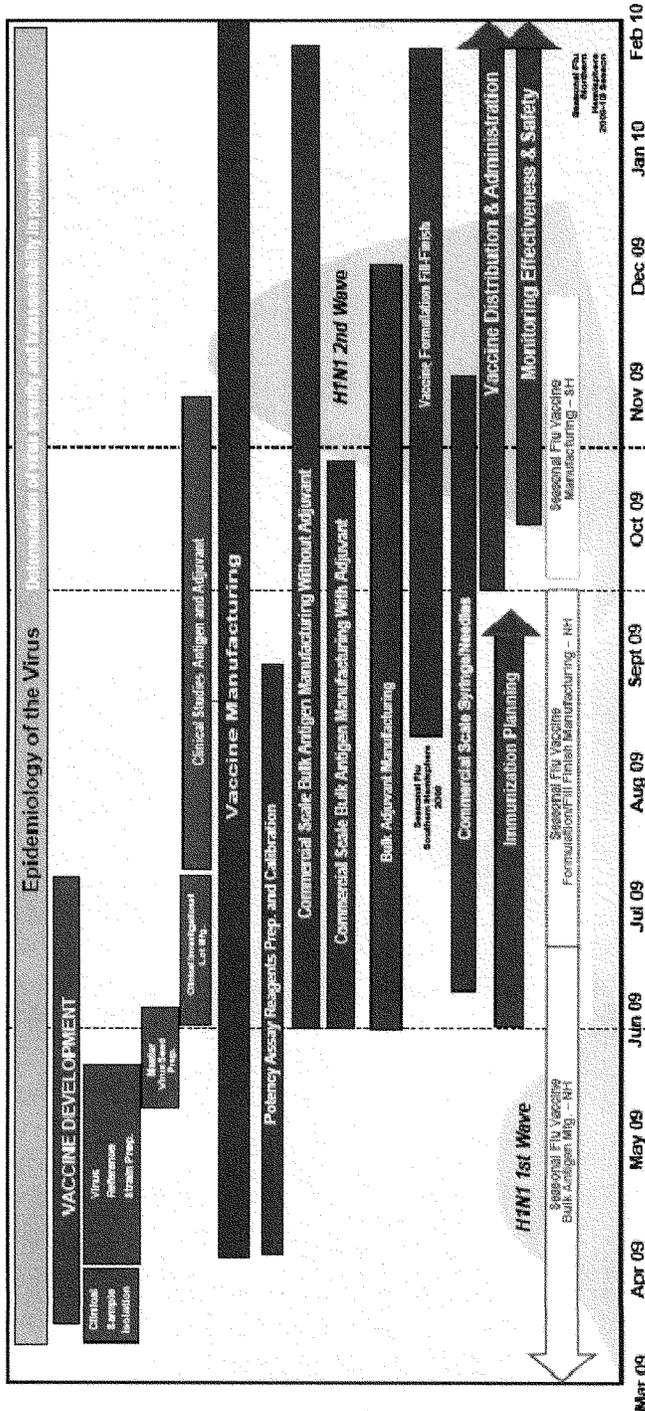
that are better prepared for a flu pandemic and can withstand, absorb, and adapt to other public health incidents before they become emergencies. Moreover, these investments require our continued attention and commitment over the long-term and should not depend solely on the occurrence of a public health emergency. Our experience with 2009 H1N1, and the lessons we have learned, demonstrate a need to examine new paradigms for leveraging the public health infrastructure and our healthcares systems to develop the needed capabilities to ensure every community is prepared to respond to and recover from future disasters.

Thank you for your time and interest. I am happy to answer any questions.



ASPR/BARDA 17 Nov 0

# U.S. 2009-H1N1 Vaccine Strategy



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**Alex Garza, MD, MPH  
Assistant Secretary for Health Affairs and  
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U.S. Department of Homeland Security**

**Written Testimony on  
“H1N1 Flu:  
Getting the Vaccine to Where it is Most Needed”**

**Before the U.S. Senate  
Committee on Homeland Security and Governmental  
Affairs**

**Dirksen 342  
November 17, 2009**

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Chairman Lieberman, Ranking Member Collins and members of the Committee, thank you for taking the time today to discuss the national response to 2009 H1N1 flu. The Office of Health Affairs (OHA) is a key player in the Department of Homeland Security's (DHS) efforts to ensure the nation is prepared for and can respond to 2009 H1N1 influenza, and I welcome the opportunity to provide this update. DHS' partnerships with the Department of Health and Human Services (HHS), including the Assistant Secretary for Preparedness and Response (ASPR), the Centers for Disease Control and Prevention (CDC), and other federal departments and agencies continue to play a critical role in our efforts. I am honored to testify with my colleagues from ASPR and CDC today.

As the Secretary testified before this Committee a few short weeks ago, the nation has learned valuable lessons from what has happened so far in the 2009 H1N1 outbreak. We continue to monitor the pandemic as well as for any signs of seasonal influenza emergence. DHS has worked in close collaboration with the Department of Health and Human Services (HHS) and other agencies to lead a strong response since the initial appearance of 2009 H1N1 flu in the spring, and we have implemented changes to continually improve our response both now and in the future.

#### **Lessons Learned and Accomplishments**

As the Secretary has previously stated, based on what we learned since the spring about 2009 H1N1, the federal government has updated its response plans, enhanced our community mitigation planning and guidance, and improved our range of abilities. We have effectively pre-deployed antiviral medications, and we have created and disseminated messages that help the public understand what the nation is facing. These improvements are not only critical to our 2009 H1N1 response, but are also critical to responding to future pandemics.

The Department and other federal agencies have been planning for an influenza pandemic for many years. We learned this past spring that much of what actually occurred in the 2009 H1N1 outbreak did not follow some aspects of prior pandemic planning which focused on threat from the H5N1 avian influenza virus. Since the spring, DHS has led interagency efforts to develop and implement H1N1-specific preparedness and response planning activities. The Office of Health Affairs has been intimately involved in these efforts. On Aug. 25, 2009, Secretary Napolitano signed the *DHS 2009-H1N1 Influenza Implementation Plan*, which identified specific roles and responsibilities across the Department, and directed all DHS components to develop plans that address key preparation and response actions, performance of mission essential functions, workforce protection, continuity of operations, and communications with key stakeholders during the H1N1 influenza outbreak.

#### **Interagency Coordination**

Throughout the response to 2009 H1N1, DHS has engaged continually and closely with federal interagency partners, including HHS, the Department of Education, the Department of State, the Department of Defense, and the White House. In addition, DHS, along with our federal partners, has worked with state, local, tribal, and territorial government and private sector partners to help mitigate and monitor the spread of this illness.

The National 2009 H1N1 Summit, held on July 9, brought together the Secretaries of DHS, HHS and Education, other federal officials and experts, staff from governors' offices, state, tribal and territorial health, education, and emergency management/homeland security officials, and national organizations to discuss H1N1 response realities and potential scenarios for the fall. The summit was condensed into a webcast for city, county, and local officials and released on Aug. 4 to update local officials on the status of H1N1, resources available and expectations going forward.

In addition, DHS, HHS, and CDC updated guidance to help multiple segments of the private sector and academic community prepare for and respond to 2009 H1N1. DHS, HHS, and the Department of Education released updated guidance for the K-12 education community on Aug. 7; updated business guidance from DHS, HHS, the Department of Labor, and the Department of Commerce on Aug. 19,; and guidance for higher education institutions on Aug. 20. In conjunction with the business guidance, DHS, HHS, and the Small Business Administration also produced a small business guide on H1N1 preparedness.

#### **The Office of Health Affairs**

For the past three years, OHA has led the Department's pandemic preparedness activities. OHA stood up a Decision Support Cell at the first reports of the outbreak, and working with our interagency partners, continues to provide critical situational awareness to DHS leadership to assist the Secretary in coordinating the federal response. OHA also serves as the DHS representative to interagency coordinating bodies focused on 2009 H1N1 and co-leads the DHS 2009 H1N1 planning effort in cooperation with the DHS Office of Operations Coordination (OPS). Finally, OHA provides health and medical guidance to our operational components, and ensures that employees are able to execute their mission-critical functions during a pandemic.

#### **Biosurveillance**

OHA, through the National Biosurveillance Integration Center (NBIC), integrates and analyzes biological surveillance information from multiple federal, state, local and private sector partners. NBIC provides senior DHS leaders a comprehensive picture of ongoing incidents and outbreaks, both domestically and overseas, and provides the continuing capability to maintain cross-domain analysis and impact assessments of the novel 2009 H1N1 influenza pandemic.

At the direction of Secretary Napolitano, OHA, through NBIC, engaged the National Infrastructure Simulation and Analysis Center (NISAC) to assess potential infrastructure impacts of a resurgent novel-H1N1 virus. The results of the assessment effort were analyzed and reviewed through an interagency process that included the Departments of Energy, Education, and Labor. The result of this modeling effort provided important insight for senior DHS leaders on the potential impact of the pandemic on infrastructure and sector stresses. These results were widely disseminated two weeks ago to state, local and tribal partners as well as private sector partners and congressional staff. NBIC and NISAC are working with HHS and other federal agencies to conduct an updated assessment using the most up-to-date disease information and

mitigation strategies. DHS will use this information to continue to inform federal government planning and preparedness.

#### **DHS Workforce Protection**

DHS has one of the largest workforces in the federal government. The health and safety of this workforce continues to be a top priority of the Secretary, and OHA plays a critical role in helping protect the DHS workforce. OHA stockpiled personal protective equipment (PPE) and antivirals in advance of the influenza outbreak; currently PPE is pre-positioned at over 120 DHS locations and field offices nationwide and is ready for deployment as needed.

To test our internal coordination for workforce protection, OHA conducted an Assistant Secretary-level 2009 H1N1/Pandemic table top exercise on Sept. 10, 2009. The exercise was designed to help DHS offices and components identify essential functions while protecting employees during an influenza pandemic event. The forum validated operational relationships, the soundness of Secretarial decision-making processes, roles and responsibilities of DHS components, and confirmed that DHS must plan for and address long-term pandemic-related continuity issues.

Throughout the H1N1 response, OHA and the Management Directorate has provided DHS employees with new and updated guidance on a number of influenza-related topics, including use of respirators, human resources flexibilities, and vaccines and antivirals. This guidance has been disseminated to components and is available to all employees on the DHS intranet. DHS will continue to provide our employees with guidance based on the best science available.

#### **Vaccine**

DHS stands ready to provide immunization program support to HHS and state, local, and private sector partners as requested. This summer, FEMA assisted HHS in performing a state assessment of needs that included determining logistical support for vaccine distribution and administration. OHA assisted in this effort by providing expertise on the CDC's H1N1 Vaccination Distribution Plan.

OHA/DHS also participated in the deliberations of the Advisory Committee on Immunization Practices pandemic workgroup that developed the target groups for vaccination. OHA also became a DHS representative to the CDC H1N1 Vaccine Taskforce.

#### **Conclusion**

Chairman Lieberman, Senator Collins, and members of the Committee: Thank you again for this opportunity to testify on the actions we are taking to mitigate the effects of H1N1 flu. I will be glad to answer any questions you may have.

**Post-Hearing Questions for the Record  
Submitted to Dr. Anne Schuchat  
From Senator Joseph I. Lieberman**

**“H1N1 Flu: Getting the Vaccine to Where It Is Most Needed”  
November 17, 2009**

- 1. How many children have been treated with intravenous antiviral medications? Of the children who have died since the emergency use authorization was provided for intravenous antiviral medication use, how many were given this treatment option?**

As of April 15, 2010 since the Peramivir IV EUA was authorized by FDA on October 23, 2009, CDC has made product available in response to 116 clinician product requests for pediatric patients under their care who they judged to be suitable candidates for treatment with peramivir. With regard to all children who have died due to complicated 2009 H1N1 influenza virus infection subsequent to the issuance of the peramivir emergency use authorization, CDC does not track the proportion of those pediatric patients who were eligible for treatment with peramivir based on the EUA conditions of use and who may have received peramivir versus other available therapy. CDC plans to perform a program evaluation that will provide some descriptive information regarding product use in adult and pediatric patients.

- 2. How many people have been treated with intravenous antiviral medications?**

In addition to the 116 requests mentioned above, CDC has provided product in response to 1,354 requests from clinicians requesting Peramivir IV for adult patients under their care. Of these 1,354 requests, 37 requests did not require Peramivir to be shipped (already available on-site), and CDC has shipped doses for 1,317 requests from SNS.

Clinical trials of intravenous peramivir, intravenous zanamivir, and intravenous oseltamivir are another mechanism by which some patients might receive intravenous antivirals. Such clinical trials have been posted on ClinicalTrials.gov by the manufacturers of the respective drugs. The sponsors of these products have the most recent information regarding number of patients enrolled. Physicians sometimes also request intravenous antivirals for individual patients not eligible for clinical trial enrollment, via the single-patient Emergency Investigational New Drug (EIND) expanded access process, subject to agreement by the product sponsor and the FDA. FDA provides information on its website about expanded access and about ClinicalTrials.gov, and responds on an urgent basis to EIND requests. However, only limited follow-up information is typically received from EIND uses of investigational products.

- 3. How many people who subsequently died were treated with intravenous antiviral medications?**

Under the conditions of the FDA-issued EUA for intravenous (IV) peramivir, all healthcare providers and the institution that requested, received, and administered peramivir IV are required to comply with product accountability and MedWatch reporting to FDA of selected adverse events (including death) that occur during peramivir IV treatment irrespective of causality or association to the product within seven calendar days from the onset of the selected adverse event. As of April 15, 2010, the CDC has released approximately 1300 treatment courses of intravenous peramivir. As of April 5, 2010, FDA received MedWatch reports for an estimated 279 patients; 134 reports cite death as an outcome. The majority of these patients were generally critically ill at the time they first received peramivir IV and received this drug for symptoms and signs of 2009 H1N1 influenza infection refractory to FDA approved therapies. Many of the deaths cited in MedWatch reports are reasonably attributable to complications of overwhelming 2009 H1N1 infection (e.g., severe respiratory failure, multiple organ failure); additionally, many patients were found to have pre-existing co-morbid conditions that would be expected to increase the likelihood of complications from 2009 H1N1 influenza. In none of the reports of death did the reporter, reporting institution or FDA clinical reviewers attribute the cause of death to peramivir use. The FDA continues to receive, evaluate and follow up on peramivir-associated deaths and safety events reported to MedWatch.

**4. What is currently being done to educate physicians and broadly communicate the availability of IV antiviral medications? Has guidance been put out on this issue?**

CDC and FDA have coordinated supplemental written information regarding Peramivir EUA in addition to the FDA-issued EUA Fact Sheets which are posted on respective websites. Also available on CDC's website are various guidance documents including antiviral options for treatment of 2009 H1N1 flu, and information for treatment of special populations including pregnant women and children. CDC's website also provides information specifically highlighted for the medical community (at <http://www.cdc.gov/h1n1flu/clinicians/>).

In addition to the website, CDC has provided information regarding EUA Peramivir IV to healthcare providers through its communication network with external partners. A few key communication and outreach activities regarding EUA Peramivir IV are noted below.

- CDC participated in weekly conference calls starting the week of October 26 with state and local public health officials to notify them of the availability of peramivir;
- CDC notified clinical partners via specialty group liaisons;
- Clinician Outreach and Communication Activity (COCA) network call on October 26: Clinical Information Call on Antiviral Treatment Options in Critically Ill 2009 Influenza H1N1 Patients;
- COCA Clinical ICU call on Oct. 28th: peramivir discussed as treatment option for hospitalized patients.

**Post-Hearing Questions for the Record  
Submitted to Dr. Anne Schuchat and Dr. Nicole Lurie  
From Senator Mark L. Pryor**

**“H1N1 Flu: Getting the Vaccine to Where It Is Most Needed”  
November 17, 2009**

1. **States have not received the amounts of the H1N1 vaccine originally promised, there are discrepancies in vaccine distribution between states, and Federal guidance regarding H1N1 has been updated over time (i.e. school closings).**
  - a. **What are the “lessons learned” from the current H1N1 pandemic, particularly with regard to vaccine distribution?**

CDC and BARDA are in the process of completing a review of the effectiveness of the 2009 H1N1 vaccine distribution process; and have some preliminary “lessons learned”. First, we found the software program to manage vaccine distribution inflexible, and not adequate to track vaccine. CDC is in the midst of replacing this program. The existing system was not nimble enough to respond to the logistical challenges imposed by same day shipping which resulted in incorrect shipments being made. Second, the provision of ancillary supplies posed multiple challenges for health care providers as they often received types and brands of needles and syringes they were not accustomed to using. Discussions are underway concerning the reconfiguration of standard ancillary supply kits for use in this type of emergency. Finally, it would have been beneficial to supply large retail pharmacies with 2009 H1N1 vaccine earlier in the vaccination campaign to ensure a wider range of venues with available vaccine, taking into account the availability of vaccine for this initiative. Similarly, national level communications to increase uptake were probably postponed more than necessary to avoid creating demand in the face of uncertain supply.

- b. **How is the federal government gathering these lessons?**

Agencies of the federal government that have been actively involved in the 2009 H1N1 influenza response have regularly evaluated their performance using a series of interim progress reviews and after action reviews to determine areas of improvement, promising practices, and lessons learned.

- c. **How are the “lessons learned” from these problems modifying current responses and being incorporated in planning for future outbreaks?**

The HHS Office of the Assistant Secretary for Preparedness and Response is leading an evaluation of the Department's response to the 2009 H1N1 pandemic. The results of this evaluation will be invaluable in informing departmental planning for future pandemics and other infectious disease outbreaks.

We also note that the chief reasons for the delays in vaccine availability were due to limited manufacturing surge capacity, priority commitments to other countries, initial start up delays on new filling lines, shortages of personnel necessary for quality review, the poor growth of the 2009 H1N1 virus resulting in reduced manufacturing yields, and seasonal vaccine production lasting longer than usual into mid-October because of production problems with one of the seasonal flu vaccine strains. Clearly, in order to avoid the problems experienced with responding to the 2009 H1N1 pandemic, an important lesson learned is that the U.S. needs to continue its support to build new U.S.-based influenza vaccine manufacturing facilities using cell-based, recombinant, and molecular technologies with greater manufacturing capacities to address these deficiencies and provide national resiliency and sufficient manufacturing infrastructure for pandemic influenza and other emerging infectious diseases. Augmenting existing egg-based vaccine manufacturing capacity with larger facilities such as the new Novartis cell-based influenza vaccine manufacturing facility in Holly Springs, NC will afford greater overall production.

**2. I hear reports from other parts of the country that some states have far fewer doses than what is needed or some individuals have faced extreme difficulties in trying to locate a physician office or clinic offering vaccines.**

**a. Why are we seeing these discrepancies among the different states?**

During the vaccine development process, states developed plans to distribute vaccine to their localities based on state priorities and in keeping with the priority groups that were recommended by the Advisory Committee on Immunization Practices (ACIP). CDC provided planning guidance to state and local vaccine planners, including a checklist for Vaccination Campaign Planning. CDC received and reviewed copies of these plans prior to vaccine distribution to ensure that they were scalable, feasible and practical. States varied in how they approached distribution based on priority groups which may have influence how vaccine became available in a given area of the country. CDC distributed vaccine to all states, four large cities (Chicago, Los Angeles, New York and Washington DC), and U.S. territories on a pro rata basis.

**b. What criteria is CDC using to determine the amount of the H1N1 vaccine distributed to the states?**

CDC's contractor, McKesson Specialty, set up four regional distribution centers to service the 62 CDC Public Health Emergency Response (PHER) grantees (50 states, DC, New York City, Chicago, LA County and six territories and Pacific Island states - also called Project Areas). CDC and BARDA worked together to order vaccine from the manufacturers and to ship vaccine to the McKesson distribution centers as vaccine was finished. Once vaccine was received at the McKesson distribution centers it was inventoried and electronically entered into the inventory management system. Once entered into the McKesson inventory management system, CDC allocated vaccine to the

Project Areas in the specific region served by a McKesson distribution center on a pro rata basis (according to the population of a Project Area).

**c. What is the vaccine distribution process beginning with how the federal government obtains the vaccine from the manufacturer and how states, localities, and even private health care professionals obtain and administer the vaccine to the public?**

Project Areas received a daily allocation report from which they could place orders with CDC. All providers, facilities or organizations wishing to participate in the H1N1 vaccination program were required to register with the state health department and sign a provider agreement. Registered providers placed orders with the state health department (usually the immunization program), which was responsible for managing the process for the Project Areas. Most Project Areas included a variety of providers or organizations, such as local health departments, healthcare facilities, private providers, occupational sites, pharmacies, schools and other sites in their ordering and allocation process. It was the responsibility of the state, and sometimes in turn, the local health departments to determine which providers could participate and how provider orders would be filled. Orders received from providers at the state health department were processed and electronically transmitted to CDC through an electronic ordering system called VACMAN. CDC, in turn, transmitted these orders to McKesson through an electronic system called NIPVAC. Once orders were received at McKesson they were filled and shipped within 24 hours. Shipping was direct to registered providers, facilities and organizations.

**d. What is required of providers and entities other than state health departments to be eligible to receive H1N1 vaccine and how does this process work?**

Eligibility to receive and administer vaccine (including physicians, clinics and hospitals) required completion of a Vaccine Provider Agreement. CDC developed the provider agreement; however states were able to include additional requirements to meet their specific needs. At a minimum, the provider agreement required that vaccine providers:

- Administer the 2009 Influenza A (H1N1) monovalent vaccine according to the recommendations of CDC's Advisory Committee on Immunization Practices as adopted by the Centers for Disease Control and Prevention.
- Store and handle the vaccine in accordance with the package insert provided with the vaccine including in compliance with cold chain requirements.
- Provide a current Vaccine Information Statement to each individual before vaccination, and answer questions about the benefits and risks of vaccination, including different indications for live versus inactivated vaccines.
- Record in the patient's medical record or in an office log the date of administration, the site of administration, the vaccine type and lot number, and the name of the immunization provider for each individual vaccinated. The record must be kept for a minimum of three years following vaccination.
- Report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System.

- Cannot charge patients, health insurance plans, or other third party payers for the vaccine, the syringes or the needles as these are provided at no cost to the provider. The provider/facility is also prohibited from selling H1N1 vaccine, syringes or needles.
- May charge a fee for the *administration* of the vaccine to the patient, their health insurance plan, or other third party payer. The administration fee cannot exceed the regional Medicare vaccine administration fee. If the administration fee is billed to Medicaid, the amount billed cannot exceed the state Medicaid administration fee.
- May either administer the H1N1 vaccine for free to individuals who cannot afford the administration fee, or refer these individuals to a public health department clinic or affiliated public health provider for vaccination.
- Must report the number of doses of H1N1 vaccine administered to individuals as requested by the state or local public health department.
- Must report to the state health department the number of doses of vaccine that were not able to be used because the vaccine expiration date was exceeded or the vaccine was wasted for other reasons. These doses must be disposed of in accordance with state regulations for biological waste.
- Are strongly encouraged to provide an immunization record card to the vaccine recipient or parent/guardian to provide a record of vaccination, to serve as an information source if a Vaccine Adverse Event Reporting System report is needed, and to serve as a reminder of the need for a second dose of vaccine (if necessary). Immunization cards were included in each shipment of vaccine.

**Foreign governments can restrict exports of necessary vaccines and our dependence on foreign vaccine manufacturers is a concern.**

**a. What contingency is there in the event that all foreign manufacturers halt exports?**

A key action in the 2006 *National Strategy for Pandemic Influenza Implementation Plan* was to expand domestic influenza vaccine manufacturing capacity to meet all U.S. needs. To that end HHS, through the Biomedical Advanced Research and Development Authority (BARDA) has supported the retrofitting of existing two vaccine manufacturing sites to produce influenza vaccine, which contributed substantially to the supply of U.S.-licensed egg-based H1N1 influenza vaccine.

In cases where the bulk vaccine was manufactured in foreign countries, formulation and fill finish manufacturing of vaccine was completed in the U.S. as soon as the bulk vaccine product became available. Other bulk products like adjuvants, which were manufactured initially outside of the U.S. during the 2009 H1N1 pandemic, were brought immediately to the U.S. as a contingency plan for storage and possible formulation and fill finish manufacturing in the U.S., if needed. Additionally, BARDA invested in cost-sharing public-private partnerships with vaccine manufacturers to build new vaccine manufacturing facilities in the U.S. to produce cell-based influenza vaccine and adjuvants. One such facility located in North Carolina opened in November 2009, became operational for adjuvant production in 2010, and is expected to become

operational for pandemic influenza vaccine production in 2011. Retrofitting of existing facilities and building new manufacturing facilities in the U.S. using cell-, recombinant-, or, molecular-based technologies, as well as adjuvants, are planned for influenza vaccine manufacturing over the next 3-5 years to meet U.S. pandemic influenza needs.

**b. How do foreign vaccine manufacturers determine and balance producing vaccines for their own country and upholding contracts with other nations to produce flu vaccines?**

There were several approaches taken by foreign manufacturers in fulfilling the U.S. commitment. Two manufacturers gave precedence to the country where the vaccine is manufactured and only provided 2009 H1N1 vaccine doses for the U.S. after they had satisfied vaccine contracts of the country of origin. Another foreign vaccine manufacturer made available their entire vaccine production capabilities towards the U.S. and completely honored their U.S. contract commitments.

**c. How does HHS ensure that contracts to produce vaccines with foreign manufacturers are upheld?**

HHS was in close communication with influenza vaccine manufacturers, and, as needed the health officials in countries where these manufacturers produced non-domestic vaccine. This communication, along with existing BARDA contracts with most U.S. licensed vaccine manufacturers, ensured that there were no unexpected exports halts on vaccine intended for the U.S.

As was the case with one vaccine manufacturer, HHS was fully briefed on the possibility that another nation would exercise their right to first available vaccine produced on their soil, and made plans accordingly. The vaccine manufacturer worked closely with HHS/BARDA to provide HHS-contracted vaccine at the very first opportunity, and this vaccine was available in the fall of 2009.

**d. Have any foreign manufacturers indicated that they have been or may be prohibited by their governments from exporting vaccine to the US?**

As was the case with one vaccine manufacturer, HHS was fully briefed on the possibility that another nation would exercise their right to first available vaccine produced on their own soil, and made plans accordingly when that country and the manufacturer completed a contractual arrangement. The vaccine manufacturer worked closely with HHS/BARDA to provide HHS-contracted vaccine at the very first opportunity, and this vaccine was available in the fall of 2009.

**e. What percent of US H1N1 vaccine needs is being produced by foreign manufacturers?**

Nearly 50 percent of the 2009 H1N1 vaccine manufactured for the USG was produced in the U.S.

3. **In response to reports that Goldman Sachs, Citibank and other large companies received vaccines, federal officials said that this was a legitimate, effective distribution method and doses delivered were intended for high risk citizens only. However, regardless of who receives the vaccines the federal government may not know whether or not vaccines are reaching the intended populations.**

- a. **How can and do you ensure that the H1N1 vaccine is in-fact directed to those high-risk populations and not others?**

The H1N1 vaccine campaign, like all other vaccine campaigns, relies on strong implementation of plans at the state and local level, and it is up to state and local health departments and immunizations programs to carry out the ACIP's recommendations. State and local immunization programs have planned their efforts according to local capacity and needs, and they have developed strategies to get vaccines to clinics and programs that can provide services to those persons at highest risk for infection or severe illness. In some instances, immunization programs have focused on a subset of priority groups while in other areas programs have found it to be more efficient to focus on all of the initial target groups.

CDC has made it clear that it expects all 62 PHER grantees to ensure that all vaccinators chosen by state and local health departments adhere to ACIP's recommendations and to clearly communicate to health care providers and the public on the rationale for the development of priority groups and distribution of vaccine in their jurisdictions. To help enforce this, vaccinators must sign an agreement prior to receiving vaccine doses. This agreement states that they will adhere to protocols and policies for vaccine administration, including an agreement to administer the 2009 H1N1 monovalent vaccine according to ACIP's recommendations.

- b. **Is there a federal effort to monitor distribution of H1N1 vaccine at the state and local levels, and if so, who is responsible for this monitoring function?**

CDC has monitored and tracked the allocation, ordering and shipping of available doses to the 62 project areas. However, the state, city or territory is responsible for tracking and monitoring vaccine doses once they arrive within the state.

4. **What is the federal government doing, if anything, to manage demand for 2009 H1N1 vaccine?**

Since the 2009 H1N1 vaccine first became available in October 2009, the demand for the vaccine has changed. In the first several months, the demand was high, in keeping with widespread disease. As the number of cases decreased, the demand decreased as the availability of vaccine increased. The plans developed by states to distribute vaccine throughout their localities focused on vaccinating priority populations first. To manage demand during a time of extreme shortage, the ACIP developed a subset of the initial priority groups to help states make decisions on where to focus their efforts. As vaccine became more readily available, states eased their restrictions to allow individuals outside

of the priority groups to be vaccinated. In December, CDC Director Dr. Thomas Frieden issued a statement to state health officers encouraging them to "... expand vaccine availability to all who wish to receive the H1N1 vaccine [where] appropriate for areas that have been able to meet demand among the priority population groups". By the end of 2009, all states had opened up vaccine to all who wished to be vaccinated.

**5. As the vaccine may not be available to all priority groups and the general public until the end of the year, what steps are federal agencies taking to ensure that the public continues to get vaccinated?**

As mentioned above, since the 2009 H1N1 vaccine first became available in October 2009, the demand for the vaccine has changed. In the first several months, the demand was high, in keeping with widespread disease. As the number of cases decreased, the demand decreased as the availability of vaccine increased. To continue promoting vaccination through periods of decreased demand, CDC has taken steps including:

- Increased marketing through National Influenza Vaccine Week. Held during the week of **January 10–16, 2010**, National Influenza Vaccination Week is a national observance that was established to highlight the importance of continuing influenza vaccination, as well as fostering greater use of flu vaccine after the holiday season into January and beyond.
- Distribution of vaccine through pharmacy chains and retail based clinics. In January, 2010, CDC began direct distribution of vaccine doses to 10 major national pharmacy chains to make more vaccine doses available to the public at convenient locations. This effort resulted in an additional five million doses being available through those settings.
- Providing states with PHER Phase IV funding opportunity to promote increased outreach to targeted populations, including those who have had historically low rates of vaccination.

**Post-Hearing Questions for the Record  
Submitted to Dr. Anne Schuchat and Dr. Nicole Lurie  
From Senator Claire McCaskill**

**“H1N1 Flu: Getting the Vaccine to Where It Is Most Needed”  
November 17, 2009**

1. **How many manufacturers did the federal government contract with for vaccinations and what are the names of each company?**

All five U.S.-licensed manufacturers of seasonal influenza vaccine, including sanofi pasteur (Swiftwater, PA), MedImmune (Speke, UK/ Philadelphia, PA), Novartis (Liverpool, UK), Commonwealth Serum Laboratories (CSL; Melbourne, Australia/ Kankakee, IL), and GlaxoSmithKline (GSK; Ste Foy, Canada) provide 2009 H1N1 vaccine to the U.S..

2. **How much has the federal government paid to each manufacturer for production?**

The USG has paid \$1.6 billion to the manufacturers for submitted and accepted invoices as of March 16, 2010.

Vaccine Manufacturer	Totals
CSL	\$99 million
GSK	\$24 million
MedImmune	\$436 million
Novartis	\$548 million
sanofi pasteur	\$514 million

3. **How much vaccine have we received from each manufacturer? Is this compliant with their contractual obligations?**

HHS ordered 229 million doses of bulk vaccine (vaccine concentrate) from the five vaccine manufacturers, including 25 million doses for international donation and 2.7 million doses on behalf of DoD. The manufacturers have completed production of all the bulk H1N1 vaccine for the 2009-2010 season.

<b>Vaccine Manufacturer</b>	<b>Bulk Doses Ordered and Delivered</b>	<b>Filled Doses Ordered</b>	<b>Doses Not Received or Recall Returns (Estimated)</b>	<b>Filled Doses Delivered</b>
<b>CSL</b>	14,000,000	7,542,830	80,000	7,462,830
<b>GSK</b>	7,600,000	7,600,000	3,975,300	3,624,700
<b>MedImmune</b>	41,900,000	32,900,000	500,000	32,400,000
<b>Novartis</b>	80,000,000	60,000,000	0	60,000,000
<b>sanofi pasteur</b>	85,330,100	88,330,000	5,700,000	85,730,000
<b>TOTAL</b>	<b>228,830,100</b>	<b>196,372,830</b>	<b>10,255,300</b>	<b>186,117,530</b>

The CSL and GSK dose shortages are due to failure to deliver filled doses on time. The SP and MedImmune shortfalls are due to non-safety recalls that resulted in doses not being shipped or returned to the manufacturer.

**4. Have all manufacturers complied at least in part with their contracts? If not, how are they noncompliant?**

Yes, all manufacturers have complied with their contracts. It should be noted that the original estimate from last summer was that we would need as many as 600 million doses to cover the entire U.S. population. When clinical results showed that only those ages 9 and under would need two doses and everyone else one dose, the number needed was dropped to about 340 million doses. As information on uptake and public desire for the vaccine became available, the number was revised downward. By the beginning of December it was determined that 229 million doses would be sufficient.

**5. Other than the delays mentioned in your testimony are there other reasons we are behind in production?**

The limited manufacturing surge capacity, priority commitments to other countries, initial start up delays on new filling lines, shortages of personnel necessary for quality review, the poor growth of the 2009 H1N1 virus resulting in reduced manufacturing yields, and seasonal vaccine production lasting longer than usual into mid-October because of production problems with one of the seasonal flu vaccine strains were the chief reasons for the delays in vaccine availability. Continuing to build new U.S.-based influenza vaccine manufacturing facilities using cell-based, recombinant, and molecular technologies with greater manufacturing capacities can address these deficiencies and provide national resiliency and sufficient manufacturing infrastructure for pandemic influenza and other emerging infectious diseases.

**6. What are we doing to make sure that industry is holding up their end of the bargain – we are spending billions of dollars, how do we know industry is not giving us the short end of the stick?**

HHS has now received all its vaccine orders and any American who wants to be vaccinated should be able to do so. Despite initial delays, millions of doses of safe H1N1 vaccine have been ordered by the states. As of March 12, 2010, 149,977,200 H1N1 vaccine doses have been allocated to the states.

**7. Do you think manufacturers were forthright with us when they provided the original projections for production?**

Yes. HHS has said from the start that flu is unpredictable, and so is the production of flu vaccine. Initial vaccine production took longer than manufacturers expected because of the time it took to grow the virus for the vaccine. This is not unusual and in fact several manufacturers extended their 2009-2010 seasonal vaccine production campaign because of poor virus growth. Also, two manufacturers were obligated to provide the vaccine in-country before they could fulfill their orders to the United States.

**8. If it weren't for the delays you described in your testimony would we have met the original targets for production?**

It is difficult to definitively say what would have happened in the absence of the delays that occurred. But it is important to note that our original production estimates were very conservative, by design. As a result, we have every reason to believe that the original targets for production would have been met had not these problems occurred. An important lesson learned is that we need to continue our investments in building US vaccine manufacturing infrastructure and in cell-based, recombinant and molecular vaccine manufacturing technology in order to avoid the problems experienced with responding to the H1N1 pandemic.



**Senate Committee on Homeland Security and Government Affairs**  
**H1N1 Flu: Getting the Vaccine to Where It Is Most Needed**  
**Testimony for the Record of Jeffrey Levi, PhD**  
**Executive Director, Trust for America's Health**  
**November 17, 2009**

Chairman Lieberman, Ranking Member Collins and members of the Committee: Thank you for the opportunity to comment on issues related to the preparation and response to the 2009 H1N1 novel influenza A pandemic. Trust for America's Health (TFAH) is a nonprofit, nonpartisan advocacy organization dedicated to saving lives by making disease prevention a national priority. For the past five years, TFAH has advocated for increased investments in preparedness and response to a potential influenza pandemic. We have published numerous reports focused on these issues, including two related to the current H1N1 pandemic.

While I understand that today's hearing is a result of considerable frustration with the current H1N1 vaccination program, I want to emphasize four critical points:

- The public health system at all levels of government has moved with remarkable speed in getting vaccines to as many Americans as supply has permitted. We have moved as fast as or faster than any other country in the world. The United Kingdom, for example, just began its vaccination campaign in late October -- even though there is more vaccine production capacity in the U.K. than in the U.S. Similarly, the French vaccination campaign did not begin until last week.
- The vaccine is well matched to the circulating virus. It is proven to be safe and effective in clinical trials. The H1N1 vaccine offers the best protection against the disease available to the American public.
- Whatever our concerns with production capacity are today, had the federal government not made the multi-billion dollar investment in enhanced vaccine production capacity since 2005, we would be in far worse shape. The limits on supply we are experiencing today are the limits imposed by the science and technology. We are depending on an inherently unpredictable technology and we are, unfortunately, still a few years away from U.S. approval of newer, more reliable technology.
- The federal government has been remarkably transparent with the American people about this pandemic since it began last spring. The federal effort appears to be well coordinated with all cabinet and subcabinet officials working from the same playbook. Public health officials have leveled with the American people -- making appropriate adjustments in recommendations as our understanding of the nature of the pandemic has evolved. The same has held true as supply issues have

arisen. While I cannot speak to when senior Administration officials should have known about serious supply problems, when they did become aware of them, they adjusted policy and messaging appropriately. This has led to some understandable confusion among the public, but it has reflected an honest attempt to reflect the current state of knowledge.

**Current production capacity reflects the pay-off of a multi-year investment.**

While there is understandable dissatisfaction with the current vaccine production levels, it is important to note that if this pandemic had hit in 2005, getting a vaccine to the American public within six months would likely have been nearly impossible. In 2005, only two manufacturers were licensed to produce influenza vaccine in the U.S.<sup>1</sup> The Department of Health and Human Services' (HHS) Pandemic Preparedness Plan, issued in November 2005, called for increasing domestic pandemic vaccine manufacturing capacity to inoculate 300 million persons within six months of the onset of an outbreak.<sup>2</sup> Government officials estimated that this capacity would take approximately five years to ramp up. According to a 2008 Congressional Budget Office (CBO) analysis, the maximum capacity for a 2006-2007 pandemic flu vaccine would have been 120 million doses (of which 50 million would have been produced domestically).<sup>3</sup>

Today, the Centers for Disease Control and Prevention (CDC) and HHS estimate there will be enough vaccine for every American, between domestic and foreign production. The near-term availability of sufficient pandemic vaccine, albeit slower than hoped for initially, is due to an investment that began in FY 2006, when Congress approved \$3.2 billion for advanced development, infrastructure building, and purchase of vaccines.<sup>4</sup> The federal government invested in retrofitting and expanding capacity in vaccine manufacturers that had domestic production facilities -- MedImmune and sanofi Pasteur - - and ensuring a year-round supply of eggs.<sup>5</sup> HHS also developed contracts with foreign-based facilities to develop vaccine for the U.S. market. By mid-September 2009, the U.S. Food and Drug Administration (FDA) had approved four companies to produce H1N1 vaccine for the U.S.,<sup>6</sup> earlier than any European country, and a fifth, GlaxoSmithKline, was licensed by the FDA last week. Six companies have also received advance development contracts for building U.S. cell-based vaccine production facilities, and the most successful companies should receive additional contracts to bring production online.<sup>7</sup>

<sup>1</sup> *A Killer Flu?* Trust for America's Health, June 2006. p. 10. Available from: <http://healthyamericans.org/reports/flu/Flu2005.pdf>

<sup>2</sup> BARDA Influenza and Emerging Disease Program. Available from: <https://www.medicalcountermeasures.gov/BARDA/MCM/panflu/panflu.aspx>.

<sup>3</sup> Congressional Budget Office, U.S. Policy Regarding Pandemic-Influenza Vaccines, Sept. 2008. Available from: <http://www.cbo.gov/ftpdocs/95xx/doc9573/Frontmatter.1.2.shtml>.

<sup>4</sup> DHHS, Report to Congress: Pandemic Influenza Preparedness Spending, January 2009. Available from: <https://www.medicalcountermeasures.gov/BARDA/documents/hhs/panflu-spending-0901.pdf>

<sup>5</sup> CBO, 2008.

<sup>6</sup> U.S. FDA, "Influenza A (H1N1) 2009 Monovalent." Available from: <http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm181950.htm>.

<sup>7</sup> CBO, 2008.

**New technologies for vaccine production are not yet FDA-approved. Use of technologies that might be perceived as “experimental” could undermine public confidence in a pandemic vaccine.**

There has been some debate about whether the United States could have used emergency authorities held by the FDA to permit different vaccine technologies to be used during this pandemic campaign so as to speed production and/or increase the amount of vaccine available. To date, the FDA has not approved cell-based vaccines, a technology whose development the U.S. government is supporting and is the basis for production of some pandemic (and seasonal) vaccine in Europe. Cell-based vaccine is more stable and allows for a faster production process. Similarly, some countries are using vaccine that contains an adjuvant -- a chemical additive that permits use of smaller doses of the actual vaccine thus dramatically extending the supply. While swift assessment of these technologies by U.S. officials is certainly called for, use of these technologies during the current pandemic would have been unwise. Given the very high level of skepticism in the U.S. (and around the world) about vaccines in general and some of the concerns about the pandemic vaccine in particular, it has been critical for federal officials to reassure the public that this is the very same vaccine manufacturing process that hundreds of millions of Americans have taken safely to protect themselves against seasonal flu. Clinical trials for this pandemic vaccine were thorough and efficient, providing additional reassurance to the American people. Approval of cell-based vaccines against a novel influenza virus, when not currently approved for the seasonal virus, would have been considered experimental by many Americans. There may have been a misperception that the vaccine had not gone through the usual rigorous FDA approval process. This would have complicated efforts to encourage all Americans, especially those at highest risk, to receive a vaccination against the H1N1 virus.

With respect to the use of adjuvanted vaccine, which is currently not approved by the FDA for seasonal or pandemic flu, those nations using it have found it to be controversial due to public perceptions. In Germany, for example, there have been protests because government officials were given a non-adjuvanted vaccine, while the public is receiving an adjuvanted vaccine. Some German professional medical societies are now recommending against the use of an adjuvanted vaccine for anyone.

**The government has moved as rapidly as possible to move vaccine from production lines to vaccine clinics. Using a centralized distribution system has assured equitable geographic distribution of a limited supply.**

As vaccine supplies have become available, the federal government has assured that vaccines have moved as quickly as possible to local vaccination sites. The government could have waited until a sufficient amount of vaccine was on hand before beginning to distribute it to immunization sites. This *may* have reduced some of the confusion we have experienced as delivery expectations were repeatedly revised downward. But this would have resulted in delaying the protection of millions who are at risk.

The policy decision that the federal government should be the central purchaser and distributor of vaccine was wise from public health and ethical standpoints. Centralization has permitted the federal government to control the flow of the limited supply. Every state is receiving vaccine on a per capita basis, rather than based on private ordering, state budgets, population demographics, or political decision-making. An influenza outbreak does not acknowledge or respect state borders, and no American should be less protected based on where he/she lives. If the federal government had depended on a private distribution system, as the previous Administration had suggested, we likely would have seen a repeat of the 2004-2005 seasonal flu vaccine shortage scenario -- wherein some providers would have sufficient vaccine, while others would have little or none, depending entirely on which vaccine manufacturer had been contracted with to supply vaccine. Although all states are temporarily experiencing shortages, all states are suffering shortfalls equally. The situation is not always as clear on the local level, where distribution within states appears uneven in some cases.

This is not to say that there have not been glitches in this new, untested, centralized system. But as best TFAH can determine, federal health officials have moved as rapidly as possible to address the problems.

**Supply shortages, the recession, and a decentralized approach to administration of vaccines in each local community contributed to varying capacity at the local level and confusion among the public.**

While the federal government has assumed centralized responsibility for vaccine distribution to state and local health departments, each locality is then responsible for developing its own policies and systems for administration of vaccine as it becomes available. This has posed a number of important challenges, particularly in a context of changing messaging resulting from shortages of both seasonal and H1N1 vaccines:

- First, local officials received constantly shifting information about how much vaccine would be available and when. This makes setting parameters for vaccine administration very difficult. It is nearly impossible to know why the communications breakdown between federal officials and industry occurred with regard to the pace of production. But this is clearly an issue that has not only created confusion among the American people; it has also made the job of local health officials far more difficult in an already challenging situation.
- Second, the largest mass vaccination campaign in U.S. history is taking place during an economic recession and when state and local health departments are experiencing devastating losses. According to a survey by National Association of County and City Health Officials (NACCHO), 15,000 positions have been lost in local health departments since the beginning of 2008. While the federal government has rapidly pumped almost \$1.5 billion to state and local health departments for pandemic response, this does not address the underlying decline in the core capacity of health departments. We are seeing the result of decades of under-investment in public health capacity. It cannot be rebuilt on an emergency basis.

- Third, public confusion may well have been exacerbated by the fact that each state and locality has determined how to distribute its supply once received from the federal government. While all jurisdictions have kept to the general prioritization of certain populations, they have often acted differently in terms of which individuals within the prioritized grouping would get vaccine first. This may well have been due to how supply was ordered by the states and/or distributed within the states. For example, some localities have prioritized health care workers, some have prioritized the vaccination of children, and still others have made pregnant women a top priority. Population demographics differ from state-to-state, so it is sensible to allow some flexibility between locales (for example, if the pandemic had targeted seniors, Arizona and Florida may have very different distribution plans than other states). However, the wide variation in distribution methodologies has created a fair amount of confusion among the public. Although each health department based their plans on a larger supply of vaccines, HHS may want to revisit this issue and consider some standardization in future emergencies since it is not unreasonable for the American people to expect some level of consistency in approach. Otherwise, they may think that the target population hierarchies articulated by the federal government are not science-based.

**Near-term and long-term next steps:**

It is our hope that this hearing will contribute to the public's understanding of the complexities of the current pandemic influenza vaccine campaign. Among the key initiatives TFAH maintains are critical to the success of the response to this and future pandemics are:

- An education campaign is needed to assure the American people about the safety and effectiveness of this (and other) influenza vaccines and all vaccines in general. It is important to remind Americans that even with the delays in vaccine availability, they should get vaccinated as soon as they can. It is not clear that the pandemic has peaked, and even if it has, many who might yet get sick are still at risk and could be protected by a vaccine. Moreover, historically there is always the danger of a third pandemic wave, which may or may not be more severe than the previous two waves. So being vaccinated now will be critical protection for those who have not become ill during the initial waves.
- FDA should move forward in assessing new technologies that are already in use in influenza vaccines in other countries -- including use of adjuvants and cell-based vaccines. If data from other countries do not meet FDA's standards, FDA should work closely with industry and the National Institutes of Health (NIH) to collect the data needed for decision making.
- Congress and the Administration should come to a consensus on what is an appropriate level of investment in new technologies. This pandemic has demonstrated that the nation still has a long way to go, not just in vaccine technology, but with regard to diagnostics and antiviral treatments as well as personal protection equipment for those exposed to influenza in the workplace.

The Biological Advanced Research and Development Agency (BARDA) has been chronically underfunded since its inception. Its support is critical to moving promising developmental technologies into mass production. Professional estimates suggest BARDA needs an annual appropriation of \$1.7 billion, rather than the current \$275 million, to achieve its mission.

- We need to provide ongoing support to state and local health departments in building capacity to respond to pandemics and other public health emergencies. As discussed previously, this emergency has occurred at a time of state and local level budget crises, with associated reductions in the public health workforce. Federal support for preparedness has been inconsistent at best. Until the emergency funds provided this summer to state and local health departments, no funds for pandemic preparedness had been appropriated since FY 2006. Underlying preparedness funding has been declining over the last several years as well, down 27 percent since FY 2005 in inflation adjusted dollars. Congress must assure a consistent level of preparedness capacity at state and local health departments on an ongoing basis. Just as we don't fund fire departments at the moment a fire breaks out, we must move away from the emergency funding mechanisms to respond to public health emergencies. This is one reason TFAH supports the mandatory funding for core public health functions that is part of the House health reform bill.
- Congress and the Administration must also address several other critical aspects of pandemic response capacity. These include:
  - Replenishment of the Strategic National Stockpile (SNS) for supplies that have been distributed to the states. This includes N-95 respirators, surgical masks, and antivirals. To our knowledge, to date only the depleted supply of pediatric formulation of Tamiflu has been ordered for restocking. We do not know what demand a future wave of this pandemic strain will require of the SNS; nor can we forget the potential for other pandemic strains emerging -- such as the H5N1 bird flu that was of primary concern until last spring.
  - Heretofore, most health system preparedness funding has been focused on a hospital-based response, whereas in this pandemic, we have seen significant overload in the ambulatory care system. We need to examine the impact this pandemic has had on hospital and ambulatory care systems and reassess whether our preparedness plans have provided an appropriate level of support to *all* aspects of the health care system.

### **Conclusion**

The 2009 H1N1 influenza pandemic has both shown our government at its best and highlighted many of the ongoing weaknesses in our public health system. As we continue to ramp up our response to this pandemic -- and provide the protection the American people rightfully expect their government to make available -- we must also take the steps necessary to assure that when the next public health crisis occurs, a stronger system is in place and capable of responding quickly, effectively, and nimbly.

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**United States Senate**  
 COMMITTEE ON  
 HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS  
 WASHINGTON, DC 20510-6250

October 26, 2009

The Honorable Kathleen Sebelius  
 Secretary  
 U.S. Department of Health and Human Services  
 200 Independence Avenue, S.W.  
 Washington, DC 20201

Dear Secretary Sebelius:

As the President acknowledged just a few days ago, the nation is facing an emergency in responding to the H1N1 epidemic. A primary concern for nearly every American at this time is the lack of sufficient vaccine supply even for those at high risk for serious complications, including children, young adults, and pregnant women. The Department of Health and Human Services (HHS) originally projected that it would have at least 40 million doses available by the end of October. More recently, however, HHS downgraded this amount to just 28 to 30 million doses by that time. As I pointed out to you last week at the H1N1 hearing held by the Senate Homeland Security and Governmental Affairs Committee, the lack of sufficient supply is alarming.

I am troubled that HHS has assured the public since August that the government would have enough vaccine to meet demand. It now appears that much of the vaccine could arrive only after many people have already been infected with H1N1. Indeed, an October 15, 2009 Purdue University study predicts that nearly 60 percent of the American population will be infected with H1N1, that a third of them will fall ill, and most disturbingly, that the peak week of infection was this past week. It seems that HHS gave its assurance of sufficient supply in August without adequate information to make such a commitment. In addition, HHS should have noted that an adequate supply also depended on whether one or two doses were needed for the vaccine to be effective – something that was not known until September.

Before our Committee, you stated that delays in production were due to problems in the manufacturing process that have now been corrected. To ensure that actions are taken to address fully the delays in providing the vaccine to the public, I ask that you respond to the following questions by October 30<sup>th</sup>:

- What is HHS's revised schedule for distributing the full 250 million doses of H1N1 vaccine?
- When does HHS expect that there will be enough vaccine to meet the needs of all those who are in the priority groups?

- What is the estimate of the number of doses of H1N1 vaccine required to vaccinate those in the high-risk groups?
- How will HHS ensure that the currently limited supply reaches those groups in an expedited manner?
- What actions is HHS taking to recover ground lost due to the prior production delays?

There are longer-term issues as well that affect our response capability. Most experts agree that a significant limiting factor in the production of any type of flu vaccine is our dependence on egg-based production rather than cell-based technology to produce the vaccine more quickly. How soon does HHS anticipate that the United States government can shift to cell-based technology for the production of flu vaccine? What effort is HHS making to ensure that this shift in production occurs rapidly and safely?

Of the five manufacturers of the H1N1 vaccine, only one is based in the United States while the other four are foreign. In the case of a pandemic, a foreign vaccine producer will likely be compelled to prioritize the bulk of their production for their own country's consumption. What investment or policy changes should the United States undertake to ensure that the U.S. can manufacture a sufficient percentage of flu vaccine domestically?

Should you have any questions about this letter, please contact me directly or have your staff contact Asha Mathew on my Committee staff at (202) 224-8432. I look forward to your prompt response.

Sincerely,

  
Susan M. Collins  
Ranking Member

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**United States Senate**  
COMMITTEE ON  
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS  
WASHINGTON, DC 20510-6250

October 27, 2009

The Honorable Kathleen Sebelius  
Secretary  
U.S. Department of Health and Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Secretary Sebelius:

We are writing to express our strong concerns about the Department of Health and Human Service's implementation of distribution plans for the H1N1 influenza vaccine. After an impressive effort to research, test, and initiate production of an H1N1 influenza vaccine in record time, for which HHS deserves our nation's appreciation, the schedule for H1N1 vaccine manufacturing and distribution originally communicated by the government has slipped. We have heard unsettling reports of growing vaccine shortages that are leading many people to ask if enough vaccine will be produced in time for those who will need it most as the H1N1 outbreak escalates. Unfortunately, these missteps in estimating available doses of H1N1 vaccine have effects beyond just growing public frustration; they have the potential to critically undermine our vaccine distribution efforts, which depend on accurate estimates of vaccine availability.

It was only three months ago that we were told, based on reports from vaccine manufacturers, that the Centers for Disease Control and Prevention (CDC) expected 120-160 million doses by the end of October. Using those projections, the CDC's Advisory Committee on Immunization Practices (ACIP) issued recommendations on July 29, 2009, intended to provide vaccination programs and providers with information to assist in planning for vaccinating high risk populations. Those recommendations, as expanded upon in an August 28, 2009, report entitled "Use of Influenza A (H1N1) 2009 Monovalent Vaccine," addressed two scenarios. The first scenario, which presumed sufficient vaccine would be available, identified five groups comprising an estimated 160 million people in the United States who would receive priority for the vaccine. The alternative prioritization plan—described as a "just in case scenario" at a July 29 CDC press briefing—was recommended to be implemented in the event that the supply of vaccine initially available was not adequate to meet demand among the broader five priority groups. In this alternative, scenario, ACIP recommended giving priority to a subset of those groups, comprising approximately 42 million people.

Two months ago, the estimate of vaccine availability dropped to 40 million by mid-October, with 20 million additional doses rolling out every week. Last week, the estimate

dropped again. Now, only about 28 million doses are expected to be available by the end of October.

Currently, the nation is witnessing stark variability in who is able to get vaccinated and where they are able to acquire vaccine. The media has reported stories of pregnant women standing in long lines at mass clinics for hours only to be turned away as supplies run out, while others in the same community are able to obtain the vaccine by appointment from their obstetrician. There is little explanation for why one pediatrician is able to vaccinate his patients, while another has not even received a shipment.

As vaccine shortages became more apparent, we question why the more conservative 'just in case' plan was not broadly implemented. Directing the 28 million H1N1 vaccines at the 42 million highest risk individuals would presumably save the most lives and lead to a more orderly and consistent process. It would also help to prevent the long, often futile lines and growing public frustration.

We are also concerned that HHS lacks the visibility into the production processes of vaccine manufacturers, domestic and foreign, to provide more accurate and timely information of such a critical public health asset.

Ensuring that our state and local communities can effectively distribute a scarce resource depends on accurate estimates of its availability. In order to understand the ramifications that inaccurate estimates of vaccine availability have on our H1N1 preparedness and response, we ask that you respond to the following questions:

- When did HHS make the initial decision to go forward with the broader, 160 million-person distribution plan? What process, if any, was in place to revisit that decision if constrained supplies made a change in distribution plans necessary? Who at HHS is responsible for making the determination about whether or when a more focused distribution plan should be implemented?
- Have you or other HHS officials consulted with ACIP as to how its recommendations should be implemented based on the current constrained vaccine supplies? If so, when did those consultations take place and what was ACIP's recommendation?
- When HHS reviewed state vaccine distribution plans, did the Department evaluate whether states were prepared to prioritize and distribute vaccinations based on both the broader and more targeted subsets of high risk populations?
- When did HHS first learn that manufacturers would not be able to provide 40 million doses of vaccine by mid-October? How did HHS determine that this would be the case?
- When it became apparent that manufacturing problems would result in inadequate vaccine doses to meet demand, did HHS officially notify states that they should implement the more targeted subset of vaccine recommendations? If so, when did this notification take place? If not, does HHS intend to alter its recommendation to states?

- What reporting, inspection, and review procedures does HHS employ to monitor H1N1 vaccine manufacturing and finishing processes?
- What steps have and will HHS take ensure more accurate and timely reporting of vaccine availability in the future?

We thank you in advance for your time and we look forward to your prompt response.

Sincerely,



Joseph I. Lieberman  
Chairman



Susan Collins  
Ranking Member



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

October 30, 2009

The Honorable Susan Collins  
United States Senate  
Washington, DC 20510-0001

Dear Senator Collins:

Thank you for your letter of October 26, 2009 regarding H1N1 influenza preparedness. As I discussed in my testimony before the Senate Committee on Homeland Security and Governmental Affairs on October 21, my Department and this Administration remain fully engaged in the 2009 H1N1 influenza response effort, working in conjunction with governors, mayors, tribal leaders, state and local health departments, the medical community, and our private sector partners.

In response to your specific questions concerning H1N1 influenza vaccine and vaccination, I would like to emphasize that, with unprecedented speed, we have completed key steps in the vaccine development and manufacturing process: HHS scientists have characterized the virus, identified candidate strains, expedited manufacturing, and performed clinical trials and licensed four 2009 H1N1 influenza vaccines. The speed of this vaccine development was made possible due to investments made through the office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) over the past four years in advanced research and development and infrastructure building and in collaboration with the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA). The rapid responses of HHS agencies, in terms of surveillance, viral characterization, pre-clinical and clinical testing, and assay development, were greatly aided by pandemic preparedness efforts for influenza pandemics set in motion by the H5N1 outbreaks in 2004, and the resources Congress provided for those efforts.

Since September 30, when the 2009 H1N1 vaccine was first made available to states to distribute, the number of doses produced, distributed, and administered has grown steadily, and states are executing their plans for providing vaccine to high-priority populations. While modest amounts of vaccine have been made available ahead of schedule, poor production yields with the initial vaccine strains, late completion of seasonal influenza vaccine manufacturing, and equipment failures on new production lines have caused significant reductions in the manufacturers' timelines. These delays are affecting both the U.S. and global H1N1 vaccine supplies. Manufacturers assure us they are taking active steps to overcome the remaining challenges, and we are doing all in our power to help them. Updated production estimates are provided weekly to the states from HHS/CDC. Despite the delay, our goal is to ensure that everyone who wants to get vaccinated will ultimately be able to do so. HHS, through CDC, is working closely with states to ensure that vaccine gets to the public as soon as it is received. HHS/CDC has worked with the vaccine distributor to ensure same-day shipping for next-day delivery for the vast majority of orders transmitted from CDC. Additionally, the distributor is

The Honorable Susan Collins  
October 30, 2009  
Page 2

now receiving vaccine from the manufacturer seven days a week. HHS continues to offer technical assistance to, and meets regularly with, states and other partners to improve the effectiveness of the vaccination program.

Moreover, BARDA conducts regular site visits to the vaccine manufacturers – completing two earlier this week – and constantly monitors the progress of every lot produced and works to make up ground wherever possible. Also, FDA visited a third manufacturer this week. Finally, on October 29, I personally spoke with the CEOs of each of the five manufacturers to emphasize the importance of accelerating production in the coming weeks.

States will continue to receive a *pro rata* allotment of H1N1 vaccine amounts for ordering as more vaccine becomes available. State and local health departments are distributing the first shipments of vaccine to providers serving people in the Advisory Committee for Immunization Practices' (ACIP's) recommended priority groups (pregnant women, children 6 months of age through adults 24 years, health care workers and emergency medical services personnel, caretakers for infants less than 6 months of age, and those with high-risk conditions 25-64 years), and many are holding vaccination clinics in schools, hospitals, or other public venues for persons in these priority groups.

HHS, along with many infectious disease and public health experts, was concerned about the possibility of an increase in cases during the early fall. Thus, an overarching goal of the ACIP's recommendations for use of pandemic vaccine was to reduce the number of ill persons, the severity of illness, and the impact on the health care system by vaccinating as many persons as possible as quickly as possible. ACIP also wanted to target vaccination during the initial phases of the program to protect those who were at higher risk for acquiring influenza (children, young adults, healthcare personnel, and emergency medical service workers) or developing influenza complications (persons with chronic medical conditions, pregnant women, and young infants). This target group totaled an estimated 159 million persons.

These initial target groups were broad, and there was no attempt to precisely match any estimate of the projected number of doses with target group size. Previous experience with seasonal influenza vaccine programs suggested that not all persons would want to be vaccinated, and that overly strict prioritization at the federal level might actually hinder vaccine uptake. During the development of the ACIP recommendations in late July, one recurring theme was that vaccine demand and availability might vary widely in the early phases of vaccine distribution, because each program was likely to have access to a different mix of persons who wanted to be vaccinated in the initial target groups. In addition, some formulations of vaccine are only approved for certain groups. To provide maximal flexibility, within ACIP's recommended priority groups, a smaller priority group of persons at highest risk for infection or severe illness was identified (pregnant women, people in regular contact with infants less than 6 months, health care personnel or emergency medical services workers with direct contact with patients or infectious materials, children age 6 months to 4 years, and children age 5 to 18 with chronic medical conditions, totaling approximately 42 million people), to provide some guidance for vaccine use if overall vaccine supplies, or supplies of certain formulations, were less than

expected. As demand and availability allowed, programs were encouraged to expand programs to include as many persons as possible. ACIP considered local health officials and vaccination providers as being better positioned to make decisions about vaccine administration and distribution in accordance with state and local conditions, using the evidence-based framework developed by ACIP to guide their decisions. During the annual meeting of the Association of State Health Officers a couple weeks ago, HHS and CDC staff sought input on whether further recommendations to restrict priority groups would help states target vaccine. A resounding message was that states were already targeting the highest-risk populations, and that such a move would be highly disruptive to vaccination programs.

The distribution and prioritization systems going forward will remain the same as at the beginning of the vaccination campaign. As expected, immunization programs planned their efforts according to local capacity and needs, and developed strategies to get vaccines to clinics and programs that could provide services to those persons at highest risk for infection or severe illness. During the past few weeks, as the initial vaccine allocations have come out, states have had to adapt to the low initial allocation and the fact that much of the initial allocation was live attenuated (FluMist<sup>®</sup>) vaccine, which cannot be given to some people in the ACIP highest-risk groups, such as pregnant women, people with underlying health conditions, and children under two years old. In those cases, the live attenuated vaccine has been targeted – appropriately – to healthy health care workers under 50 and children two and older. In some instances, immunization programs have focused on some or all of the highest-risk priority groups, while in other areas, programs have found it to be more efficient to continue programs for the initial target groups. In most instances, states and local health officials are enabling rapid and appropriate use of their vaccine allocations. In addition, the disappointing news about vaccine supply is partly balanced by the scientific evidence indicating that only one dose will be necessary for older children and adults, which means that more persons can be fully protected more quickly than had been expected.

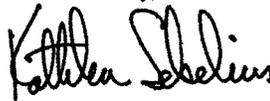
Going forward, HHS planning efforts will continue to support the advanced development of seasonal and pandemic influenza vaccines. In 2005 and 2006, the first six contracts for advanced development of cell-based influenza vaccines were initiated. Several of these contractors have made significant advances toward U.S. licensure of their cell-based influenza vaccines. One of these contractors started in 2008 to build a new state-of-the-art cell-based influenza vaccine manufacturing facility with a surge production capacity of 150 million doses of pandemic vaccine in six months using HHS/ASPR support. Additionally, HHS is supporting the advanced development of one recombinant influenza vaccine, which promises to have a shorter timeframe for production of pandemic vaccines and expects to fund development of more recombinant vaccines soon. HHS also provided cost-sharing support to expand the domestic influenza vaccine manufacturing infrastructure by retrofitting existing domestic vaccine manufacturing facilities, provided support for a secure year-round supply of eggs and other supplies for existing U.S.-based egg-based facilities, and supported the construction of new U.S.-based cell-based influenza vaccine manufacturing facilities. These investments will advance U.S. pandemic preparedness goals and decrease dependence on foreign manufacture of influenza vaccines.

The Honorable Susan Collins  
October 30, 2009  
Page 4

If you have additional questions regarding federal pandemic preparedness, please do not hesitate to contact my Office of the Assistant Secretary for Preparedness and Response, led by Dr. Nicole Lurie.

I appreciate your strong commitment to public health preparedness and look forward to continuing to work with you on these important issues.

Sincerely,

A handwritten signature in black ink that reads "Kathleen Sebelius". The signature is written in a cursive, flowing style.

Kathleen Sebelius



THE SECRETARY OF HEALTH AND HUMAN SERVICES  
WASHINGTON, D.C. 20201

November 10, 2009

The Honorable Joseph I. Lieberman  
Chairman  
Committee on Homeland Security and  
Governmental Affairs  
United States Senate  
Washington, D.C. 20510-6250

Dear Mr. Chairman:

Thank you for your letter of October 27, 2009 regarding the Department of Health and Human Services' (HHS) implementation of distribution plans for the 2009 H1N1 influenza vaccine. As I discussed in my testimony before the Senate Committee on Homeland Security and Governmental Affairs on October 21, and as we discussed in our telephone conversation, my Department and this Administration remain fully engaged in the response to H1N1 influenza, working in conjunction with Congress, governors, mayors, tribal leaders, state and local health departments, the medical community, and our private sector partners.

In response to your specific questions concerning H1N1 influenza vaccine manufacturing and distribution, I would emphasize that with unprecedented speed, HHS scientists have characterized the virus, identified candidate strains, expedited manufacturing, initiated clinical trials, and licensed four 2009 H1N1 influenza vaccines. The speed of this vaccine development was made possible due to the investments made through my Office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) over the past four years in advanced research and development and infrastructure building. The rapid responses of HHS agencies, including the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Food and Drug Administration (FDA), in terms of surveillance, viral characterization, pre-clinical and clinical testing, and assay development were greatly aided by pandemic preparedness efforts set in motion by the H5N1 outbreaks in 2004 and the resources Congress provided for those efforts.

CDC's Advisory Committee on Immunization Practices (ACIP) met in July to establish recommendations for the use of the 2009 H1N1 vaccine. HHS, along with many infectious disease and public health experts, was concerned about the possibility of an increase in cases during the early fall. Thus, an overarching goal of ACIP's recommendations for use of pandemic vaccine was to reduce the number of persons who become ill, the severity of illness, and the impact on the health care system by vaccinating as many persons as possible as quickly as possible. ACIP also wanted to target vaccination during the initial phases of the program to protect those who were at higher risk for acquiring influenza (children, young adults, health care personnel, and emergency medical service workers) or developing influenza-related

The Honorable Joseph I. Lieberman  
November 10, 2009  
Page 2

complications (persons with chronic medical conditions, pregnant women, and young infants). This target group totaled an estimated 159 million persons.

These initial target groups were broad, and there is no precise match between estimates of the projected number of doses and target group size. Previous experience with seasonal influenza vaccine programs suggested that not all persons would want to be vaccinated, and that overly strict prioritization at the federal level might actually hinder vaccine uptake. During the development of the ACIP recommendations, one recurring theme was that vaccine demand and availability might vary widely in the early phases of vaccine distribution because each state or locality was likely to have access to a different mix of persons who wanted to be vaccinated in the initial target groups. In addition, some formulations of vaccine are approved only for certain groups.

To provide maximal flexibility, a smaller priority group of persons at highest risk for infection or severe illness was identified to provide some guidance for vaccine use if overall vaccine supplies, or supplies of certain formulations, were less than expected. As demand and availability allowed, state and local programs were encouraged to expand efforts to include as many persons as possible. ACIP recommendations were designed to give states the latitude to make the best use of local distribution systems and balance local supply and demand. The advisory committee recognized that local health officials and vaccination providers are better positioned to make decisions about vaccine administration and distribution in accordance with state and local conditions, using the evidence-based framework developed by ACIP to guide their decisions. CDC is in regular contact with the states through weekly state health officer calls and other means to review state readiness for distributing and administering the vaccine in accordance with those goals.

During the annual meeting of state health officers a few weeks ago, HHS and CDC staff sought input on whether further recommendations to restrict priority groups would help states target vaccine. A resounding message was that states were already targeting the highest-risk populations, and that additional federal recommendations would be highly disruptive to ongoing vaccination programs. On October 22, 2009, ACIP met and heard an update from HHS on vaccine supply and program implementation. Committee members indicated they were satisfied that the July recommendations remained appropriate for the current situation. The presentations from this meeting are posted on the ACIP website at <http://www.cdc.gov/vaccines/recs/ACIP/slides-oct09.htm>.

Since the 2009 H1N1 vaccine was first made available to states to distribute, the number of doses produced, distributed, and administered has grown steadily, and states are executing their plans for providing vaccine to high-priority populations. There have been significant delays in production timelines due to poor production yields with the initial vaccine strains, decisions in one manufacturer's home country, late completion of seasonal influenza vaccine manufacturing, and equipment failures on new production lines. These delays are affecting both the U.S. and global H1N1 vaccine supplies.

The Honorable Joseph I. Lieberman  
November 10, 2009  
Page 3

After careful and comprehensive review of all vaccine lots produced to date and the ways these problems have been resolved, HHS believes production will continue at a better pace. Manufacturers have taken active steps to overcome the remaining challenges, and we are doing all in our power to help them. HHS, through BARDA, conducts regular site visits to the manufacturers – completing another round the week before last – and works to make up ground wherever possible. The Food and Drug Administration conducts site inspections, and I have spoken with each of the company CEOs to emphasize the importance of accelerating production in the coming weeks. Furthermore, HHS/BARDA receives daily updates on vaccine production from all manufacturers and is placing manufacturing experts at vaccine plants as needed.

In August, HHS/BARDA became aware that there were vaccine production problems, and we revised vaccine production projections downward several times over the course of August and September. The revised projections were based on three factors:

- 1) First, when the potency reagents used to determine the amount of vaccine produced became available in early to mid-August, it was discovered that the potency of vaccine strains was lower than initially expected (3-4 fold less than expected for some strains). Manufacturers addressed this problem by using new virus strains and/or adapting virus strains for high production yields, as is done annually for seasonal flu vaccine manufacturing. These changes are resulting in increased vaccine supply.
- 2) Second, seasonal flu vaccine production for the 2009-2010 season was extended much longer than anticipated this year because of production problems with one of the seasonal flu vaccine strains, reducing the number of early 2009 H1N1 vaccine production days. This reduced by over 100 the number of H1N1 vaccine lots manufactured during this time.
- 3) Last, the availability of H1N1 vaccine in October and November was reduced by the decision by one country to prioritize H1N1 vaccine production for its own population.

We further reduced projections in early October based on the full analyses of the effects of the above factors, brief interruption (now resolved) in operation of new fill-finish production lines that were put in place to handle the greatly increased downstream processing for both H1N1 vaccine and seasonal vaccine, and continued production challenges facing one of the manufacturers.

When manufacturers provided their timelines for the number of 2009 H1N1 doses expected to be available this fall, they and we at HHS provided estimates with the caveat that the numbers and dates could be negatively impacted if problems associated with the vaccine manufacturing, process like those mentioned above, arose. Unfortunately, that caveat was rarely reported in the media. While the public understandably expected the vaccine to match the earlier projections, the manufacturers faced a perfect storm of challenges that slowed vaccine production. HHS continues to work closely with the vaccine manufacturers to provide vaccine to the public as quickly as possible. HHS/BARDA receives updated production estimates from manufacturers each week. Since early October, weekly projections of H1N1 vaccine for the United States have

The Honorable Joseph I. Lieberman  
November 10, 2009  
Page 4

been provided to state health officials. CDC receives daily updates about the number of vaccine doses available for distribution from the distribution company and provides allocation information to the states daily. CDC also holds weekly press conferences, every Friday, to update the media about vaccine availability. Vaccine availability and distribution updates are also posted on CDC's website at <http://www.cdc.gov/h1n1flu/vaccination/vaccinesupply.htm>.

Despite the delays in early vaccine delivery, we continue to work to ensure that all those who need vaccine can receive it. HHS, through CDC, is working closely with states to get vaccine to the public as soon as it is received. CDC has worked with the vaccine distributor to ensure the distributor can receive shipments from manufacturers 7 days a week and can provide 24-hour turnaround time on distribution. CDC continues to offer technical assistance to, and meets regularly with, states and other partners to improve the effectiveness of the vaccination program.

The distribution and prioritization systems going forward will continue to empower immunization programs to plan their efforts according to local capacity and needs, and to develop strategies to get vaccines to clinics and programs that could provide services to those persons at highest risk for infection or severe illness. During the past few weeks, as the initial vaccine allocations have become available, states have had to adapt to the low initial allocation and the fact that much of it was live attenuated nasal spray vaccine, which cannot be given to all target groups. In some instances, immunization programs have focused on some or all of the smaller priority groups, while in other areas, programs have found it more efficient to continue programs for the initial target groups. Fortunately, the initial small vaccine supply is partly balanced by the scientific evidence indicating that only one dose will be necessary for older children and adults, which means more persons can be fully protected more quickly than had been expected.

States will continue to receive a *pro rata* allotment of H1N1 amounts for ordering, as more vaccine becomes available. On November 5, 2009, CDC sent a letter to state and local health officers to reinforce the importance of ensuring equitable access to the vaccine for the priority groups identified by ACIP: pregnant women, children 6 months of age through adults 24 years, health care workers and emergency response personnel, caretakers for infants under 6 months of age, and those 25-64 with high-risk medical conditions. Many are holding vaccination clinics in schools, hospitals, or other public venues for persons in these priority groups.

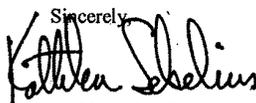
Our experience with the vaccine manufacturing process has made clear the need to enhance our country's vaccine manufacturing capability. HHS is committed to developing domestic cell-based and other technologies to increase our vaccine manufacturing capacity. This will not only help the United States; it will help the world. It is important that when the next pandemic hits, we are better prepared to mount a speedy, agile response. Going forward, HHS planning efforts will continue to support the advanced development of seasonal and pandemic influenza vaccines. In 2005 and 2006, the first six contracts for advanced development of cell-based influenza vaccines were initiated. Several of these contractors have made significant advances toward U.S. licensure of their cell-based influenza vaccines. One of these contractors started in 2008 to build a new state-of-the-art cell-based influenza vaccine manufacturing facility with a surge production capacity of 150 million doses of pandemic vaccine in six months using HHS/ASPR support.

The Honorable Joseph I. Lieberman  
November 10, 2009  
Page 5

Additionally, as you know, HHS is supporting the advanced development of one recombinant influenza vaccine, which promises to have a shorter timeframe for production of pandemic vaccines and expects to fund development of more recombinant vaccines soon. HHS also provided cost-sharing support to expand the domestic influenza vaccine manufacturing infrastructure by retrofitting existing domestic vaccine manufacturing facilities, and provided support for a secure year-round supply of eggs and other supplies for existing U.S.-based egg-based facilities. These investments will advance U.S. pandemic preparedness goals and decrease dependence on foreign manufacture of influenza vaccines.

Our response to the 2009 H1N1 virus is a comprehensive one, and we have also worked since the initial outbreak to protect the public. We have implemented a nationwide prevention campaign, published guidance aimed at reducing disease transmission and mitigating the impact of a surge in demand on the health care system, ensured access to antiviral drugs – including new intravenous antivirals – for those who become ill with influenza, and, with your help, provided \$1.44 billion in preparedness grants to states, localities, and hospitals. I provided more detailed information about these and other efforts in my letter of November 5.

I appreciate your strong commitment to public health preparedness and look forward to continuing to work with you on these important issues. I will provide a similar response to Senator Collins.

Sincerely,  
  
Kathleen Sebelius

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